IMPACT OF STATE RESTRICTIONS IN DRUG BENEFIT MANAGEMENT POLICIES ON MEDICAID DRUG EXPENDITURES

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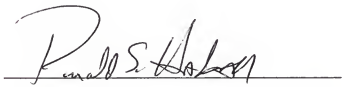

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

Supon Limwattananon
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ABSTRACT

The objective of this study is to estimate the effects of state restrictions in drug benefit management policies on Medicaid drug expenditures. The focus is on the policies that aim to discourage the excessive use of Medicaid drugs. These include prescription copayments, caps on the reimbursable number of prescriptions, and drug coverage limits due to restrictive formulary. This study pooled the cross-sectional observations of all states except Arizona and Tennessee over the five years: 1992-1996. Health Care Financing Administration (HCFA)'s Medicaid financial reports and program statistics provided the data on Medicaid drug expenditures, drug recipients and Medicaid enrollees. Data on prescription copayments, prescription limits, and Medicaid payment basis for drug ingredient costs and dispensing fee came from the annual surveys by the National Pharmaceutical Council. The non-reimbursable proportion of Medicaid drugs and mix of the reimbursed drugs were developed exclusively in this study from HCFA's public use files.

The number of copayment states increased gradually from 24 states in 1992 to 31 states in 1996. The copayment amounts in these states ranged from $0.50 to $3.00. This study found that a requirement of one dollar of copayments reduced Medicaid drug expenditures per drug recipient by 5%. Ten of the twelve states with the prescription cap policy imposed limits of 3 to 6 prescriptions per month through the five years. States that

implemented the prescription cap policy had up to 19% lower drug expenditures per drug recipient than other states. States that imposed a restrictive formulary that excluded number of drugs from Medicaid reimbursement by 1% more than other states would have a 1% lower Medicaid drug expenditures per drug recipient. The relative change in this non-reimbursement rate was not found associated with the relative change in drug expenditures in a state. This study, however, found that the market penetration of the patent-protected, single source drugs has a major impact on the Medicaid drug expenditure growth. Specifically, a 1% increase in fraction of the reimbursed prescriptions that were filled by single source drugs would increase Medicaid drug expenditures per drug recipients by 1.4%.

CHAPTER 1

INTRODUCTION

Collectively, the Medicaid programs are the largest payers for prescription drugs in the United States. States have experienced substantial increases in Medicaid expenditures for prescription drugs over the past two decades. In an attempt to control Medicaid drug expenditures, states have adopted a variety of drug benefit management policies since the beginning of Medicaid programs. Drug benefit management policies have included efforts targeted at many of the components contributing to drug expenditures including the population covered, drug utilization propensity and intensity, payment per unit of use, and the administrative costs.

These drug benefit management policies have affected each of the major actors in the Medicaid program including Medicaid enrollees, physicians, pharmacists and pharmacies, brand and generic pharmaceutical manufacturers, and the state and federal governments. Medicaid enrollees have experienced state policies such as copayment per prescription as an economic influence on drug utilization, limits on the number of prescriptions that can be reimbursed in a given period per drug recipient, and drug formulary and prior authorization restrictions aimed at ensuring utilization of appropriate drugs.

Physicians have experienced state policies such as drug formularies which have restricted the drugs that can be prescribed for Medicaid patients, prior authorization of certain drugs to ensure medically appropriate utilization, and drug utilization review

programs with feedback to prescribers. Pharmacists and pharmacies have experienced drug formulary restrictions, prior authorization requirements, fixed dispensing fees and drug product cost allowances set by the state Medicaid program, limits of drug product cost payments to the generic when an FDA-approved generic equivalent is available, requirements to dispense prescriptions even if the copay is not paid by the recipient, and enforcement of fixed prescription limits per month.

Brand and generic pharmaceutical manufacturers have experienced drug benefit management policies primarily through the Omnibus Budget Reconciliation Act 1990 (OBRA90) legislation establishing manufacturer drug rebates, while at the same time eliminating drug formulary restrictions with respect to the drugs covered. The state governments have faced the need to expand drug benefit management to implement the range of policies, which have been adopted. Both federal and state governments have had to add administrative structures to manage the drug rebate program.

The purpose of this study is to understand better the economic impact of these Medicaid drug benefit management policies on Medicaid drug expenditures. This study focuses on an estimation of the effects of restrictions that states imposed on Medicaid drug utilization. The first section in this chapter introduces the topic and the significance of the issue. Also described are the types of state Medicaid polices adopted to contain Medicaid drug expenditures. The second section presents a statement of the problem that is being addressed by this research project. The last section describes the study objectives addressed by this study.

1.1 Background and significance

1.1.1 Economics of prescription drugs

In the United States payments for drugs and other non-durable medical products constitute the third largest element of personal health care expenditures following hospital care and physician services (Levit, 1985; Levit et al., 1996). Expenditures for prescription drugs have grown much faster than economy-wide inflation during the past two decades. The ten-year average annual growth rate of prescription drug expenditures (in current-year dollars) has increased from 10.4% during 1961-70 and 11.8% during 1971-80 to 21.4% during 1981-90 period (Levit et al., 1996). The average annual growth rate has been 11.1% from 1990-1997 (Baugh, et al., 1999).

The per capita expenditures for prescription drugs in the U.S. have also grown and the rate of growth has varied by geographic region. During the period 1980-1991, states in the economic regions of New England (6 states) and Mid-east (6 states) have experienced relatively high expenditures per capita and growth rates (Levit et al., 1993). In contrast, six Rocky Mountain states and three Southwestern states had a lower expenditure per capita. Most other states had average expenditures per capita similar to the national average.

The payment source for prescription drugs has experienced a dramatic shift from out-of-pocket to third-party payments. The share prescriptions paid for by third parties has increased substantially over time from 4% in 1960 to 18% in 1970, 34% in 1980, 52% in 1990, and 71% in 1997 (Levit et al., 1996; and Baugh et al., 1999).

1.1.2 Medicaid payments for prescription drugs

Medicaid was enacted under Title XIX of the Social Security Amendments in 1965. It is an open-ended, entitlement-based program that provides grants through states for healthcare assistance to certain low-income families, elderly, and disabled persons. States have the option to participate in Medicaid and are required to follow broad federal guidelines regarding eligibility criteria, benefit coverage, and provider reimbursement in order to receive the federal medical assistance percentage (FMAP) from the federal government.

Drug coverage is not a mandated benefit under this jointly funded federal-state program. In 1967 thirty-one states chose to provide prescription drug benefits under the fee-for-service reimbursement system. By 1988, all 51 Medicaid jurisdictions offered drug benefits to their Medicaid enrollees who are eligible under the categorically needy status (Gondek, 1994). Certain states also extended Medicaid drug benefits to an individual eligible under the medically needy status (Buchanan and Smith, 1994).

The growing importance of Medicaid on financing prescription drugs is evident by the fact that Medicaid is currently the largest third-party payer for prescription drugs in the United States. Medicaid drug payments accounted for 8% of U.S. drug expenditures in 1970. By 1980 Medicaid drug expenditures had grown to 12% of U.S. drug expenditures, and to 14% by 1990 (Levit et al., 1996). In 1997 Medicaid drug expenditures had reached 17% of U.S. drug expenditures (Baugh et al., 1999).

Medicaid has experienced a continual growth in drug expenditures and the rate of growth has consistently been above the economy-wide inflation rate (as measured by the

CPI-u All Items). The average annual growth rate of national Medicaid drug payments (in current-year dollars) increased markedly from 10.2% in 1980 to 17.4% in 1993 (Schondelmeyer et al., 1995). By 1997, Medicaid drug expenditures reached $12 billion (Baugh et al., 1999). As a percentage of Medicaid total health care expenditures, Medicaid payments for prescription drugs increased from 6.8% in 1990 to 9.7% in 1997 (Baugh et al., 1999).

Table 1.1 presents time trends in total Medicaid drug expenditures along with the expenditure components based on a time-series of the national aggregate data. Reasons behind a continually increase in the Medicaid payments for prescription drugs at the national level can be explored through the decomposition of the total drug expenditures into three related components. First, relative changes in the number of the recipients of Medicaid drugs reflect effects of the change in population component. Second, effects of the change in the intensity component are indicated by the relative changes in the number of reimbursed prescriptions per drug recipient. Third, the Medicaid payment rate per prescription represents the pricing component of the Medicaid drug expenditures.

The total number of the recipients of any Medicaid services remained relatively stable at about 20 million per year during 1980-85, then rose to 23 million in 1988, then rose rapidly by 42% to 33 million in 1993 (Schondelmeyer et al., 1995). The number of the recipients of prescription drugs shows a similar time trend. Drug recipients remained relatively constant at about 14 million per year during 1979-85, then rose to 15 million in the period 1986-88, and by 1993 had reached 24 million. In 1998, the number of Medicaid drug recipients in fee-for-service sector decreased to 19.3 million.

Table 1.1

National Medicaid drug expenditures and related components, 1975-1998

Year	Drug recipients (millions)	Annual change	Prescriptions per drug Recipient	Annual change	Payments* per prescription	Annual change	Drug expenditures (millions)*	Annual change
1975	14.2		12.4		$4.64		$815	
1976	14.9	5.1%	12.4	0.2%	$5.08	9.5%	$940	15.3%
1977	15.4	3.3%	12.1	-2.6%	$5.47	7.7%	$1,018	8.3%
1978	15.2	-1.2%	12.1	0.0%	$5.88	7.6%	$1,082	6.3%
1979	14.3	-6.0%	13.0	7.5%	$6.43	9.3%	$1,196	10.5%
1980	13.7	-4.0%	13.7	4.9%	$7.04	9.5%	$1,318	10.2%
1981	14.3	4.0%	13.7	-0.1%	$7.89	12.1%	$1,535	16.5%
1982	13.5	-5.0%	13.3	-2.9%	$8.91	12.9%	$1,599	4.2%
1983	13.7	1.4%	13.0	-1.9%	$9.93	11.4%	$1,771	10.8%
1984	13.9	1.5%	12.9	-0.4%	$10.92	10.0%	$1,968	11.1%
1985	13.9	-0.1%	13.9	7.1%	$12.01	10.0%	$2,315	17.6%
1986	14.7	5.6%	14.0	0.9%	$13.10	9.1%	$2,692	16.3%
1987	15.1	2.6%	14.3	1.9%	$13.90	6.1%	$2,988	11.0%
1988	15.3	1.6%	14.5	2.0%	$14.79	6.4%	$3,294	10.2%
1989	15.9	3.9%	14.1	-2.8%	$16.41	10.9%	$3,689	12.0%
1990	17.3	8.7%	14.4	2.1%	$17.71	8.0%	$4,420	19.8%
1991	19.6	13.2%	14.4	-0.4%	$19.28	8.8%	$5,424	22.7%
1992	22.1	12.7%	14.4	0.2%	$21.36	10.8%	$6,790	25.2%
1993	23.9	8.3%	14.6	1.3%	$22.85	6.9%	$7,969	17.4%
1994	24.5	2.4%	14.8	1.2%	$25.13	10.0%	$9,086	14.0%
1995	23.7	-3.0%	15.8	6.8%	$27.06	7.7%	$10,127	11.5%
1996	22.6	-4.8%	15.9	1.0%	$30.79	13.8%	$11,080	9.4%
1997	21.0	-7.1%	17.3	8.5%	$34.27	11.3%	$12,434	12.2%
1998	19.3	-7.8%	18.0	4.0%	$38.87	13.4%	$13,522	8.7%

* in the current-year dollars

Source: Schondelmeyer et al., 1995;

Schondelmeyer SW (personal communication)

Growth in the total number of drug recipients (the population component) is characterized by sharp periodic increases in the number of people enrolled in the Medicaid program. These sharp increases result primarily from expanding Medicaid eligibility criteria under the federal legislation. Since the 1972 Social Security Amendments, Medicaid has extended the eligibility to the recipients of Supplemental Security Income and, at state discretion, certain optional categorically needy and medically needy persons. Recent federal legislation during 1980s contributed to the growth in Medicaid beneficiaries who are pregnant women and children in low-income families.

Low-income aged and blind/disabled enrollees account for a major share of Medicaid drug expenditures. In the Medicaid program, even though there are far more drug recipients who are adults and children in the Aid-to-Family-with-Dependent-Children (AFDC) families. Although constituting only 15.5% of all-eligible drug recipients, the elderly accounted for 34.8% of Medicaid drug expenditures in 1989. The annual growth rate in drug expenditures for the elderly (11.6%) was higher than the growth rate for all beneficiaries (10.4%) during 1975-1989 (Reilly et al., 1990).

The number of prescriptions per Medicaid drug recipient reflects the intensity component of Medicaid drug expenditures. This utilization-related element was relatively stable through out the years. On average, a Medicaid drug recipient reimbursed about 13-14 prescriptions each year during 1979-1992.

Among all Medicaid drug expenditure components, payments per prescription exhibited the highest rate of increase. Apart from the general inflation rate, this pricing

component of Medicaid drug expenditures is typically driven by the payment basis for filling a prescription (dispensing fee) and the payment allowance for the dispensed drugs (drug ingredient cost). Average Medicaid payment rate per prescription (in current-year dollars) rose from $4.64 in 1975 to $9.93 and $22.85 in 1983 and 1993, respectively (Schondelmeyer et al., 1995). Compared with the drug ingredient cost allowance, dispensing fee payments increased very slightly over time. The fraction of total costs represented by the dispensing fee shrank from 47% in 1975 to 31% and 18% in 1983 and 1993, respectively. Data from the national Medicaid drug expenditures show that growth in the pricing component is driven mostly by an increase in the ingredient costs of drug products.

1.1.3 Medicaid drug benefit management policies

Given the rising cost of the Medicaid program, states have been under fiscal and political pressure to control spending. Because Medicaid is an open-ended entitlement program, states cannot establish fiscal control directly through budget limits or limits on the number of health care recipients in the entitled category. Instead, state Medicaid agencies have certain flexibility in determining scope of benefits to be covered and provider payment methods. Medicaid drug cost containment is implemented mostly at the prescription reimbursement process with some forms of restrictions. The restrictive drug benefit management policies can affect various components related to the Medicaid drug expenditures.

The supply-side restrictions imposed on pharmacies usually focus on the pricing

component of the expenditures. The federal government by Health Care Financing Administration (HCFA) issues guidelines on Medicaid payment rate paid to pharmacies. Medicaid reimbursement for the ingredient costs of selected multi-source drug products is controlled by the federally listed price, known as maximum allowable cost (MAC). The federal MAC list has been effective since August 1976. By 1987, states had been given flexibility to establish their own lists of drug products subject to MAC in addition to the federal MAC list. For non-MAC drug products, the allowable drug ingredient cost, known as estimated acquisition cost (EAC) varies across states. Most states set the EAC at a fraction of average wholesale price (AWP) of drug products. Every state limits the maximum dispensing fee per prescription. States also cap the aggregate payment rate for the prescriptions of non-MAC drugs at the lowest amount between the provider's usual and customary charges to the public and the defined EAC plus the allowable dispensing fee.

At the demand side, the main purpose of a restrictive drug benefit management policy is to discourage excessive use of prescription drugs. This can affect the utilization components in either the propensity to use any drugs among all Medicaid enrollees (potential drug users), or the intensity of use among the drug recipients, or both.

1.1.4 State restrictions in Medicaid drug benefit management policies

State drug benefit management policies vary considerably with respect to breadth and depth of the restrictions imposed on Medicaid drug utilization process. These restrictive policies can be organized in two broad categories. The first category is a

requirement for patient cost-sharing usually in a form of copayment per prescription.

Under the prescription copayment policy, an individual is required to pay a flat fee out-of-pocket for each filled prescription. With the passage of Social Security Amendments in 1972 and the 1982 Tax Equity and Fiscal Responsibility Act, states have been allowed to impose nominal copayments to Medicaid drug recipients with certain exceptions for children, pregnant women, and nursing home residents. In addition, states may not reimburse pharmacies for the uncollectible amounts of copayments. The pharmacies that fail to collect the statutory copayment amounts in turn may not deny their services in case of a medical emergency.

The second category consists of administrative restrictions on quantity of prescriptions that can be reimbursed within a given period and on number or type of drug products that are covered by a formulary of Medicaid drugs. Federal regulation has allowed states to place appropriate limits on Medicaid services based on medical necessity and utilization controls. Certain states choose to enact a prescription cap policy that places limits on number of new prescriptions per month, or number of prescriptions that can be refilled within a given 5-6 month period, or both.

A restrictive drug formulary often excludes certain drug products in a therapeutic class from Medicaid reimbursement. Formulary-excluded drug products typically include newly marketed drugs, expensive drugs, drugs with marginal effectiveness, or drugs with potential misuse. Under the restrictive formulary, physicians are free to prescribe particular drugs. However, certain drug products that are not approved by the Medicaid formulary may not get reimbursed. As a consequence, Medicaid recipients

have to pay out-of-pocket the full cost of the drugs that are not covered. Even though certain drug products are not explicitly excluded, an individual prescription may require prior authorization process for the Medicaid reimbursement. Otherwise, the reimbursable substitutes have to be prescribed or dispensed instead.

1.2 Statement of the problem

Since the era of cost containment in health care in 1970s, Medicaid drug benefit management policies enacted in several states have been under public scrutiny. The economic impact of state restrictions in Medicaid drug benefit management is a relevant research question. The pharmaceutical industry has a vast financial interest in policies that affect the use of prescription drugs. Several studies related to Medicaid policy issues (Sudovar and Rein, 1978; Hefner, 1979; Hefner, 1980; Smith and Simmons, 1982; Schweitzer et al., 1985; and Moore and Newman, 1993) have been funded by the pharmaceutical companies or the industry-related organizations.

Prior economic evaluations of Medicaid drug policies do not provide consistent conclusions. Some studies, especially those sponsored by the pharmaceutical industry tend to have negative conclusions toward the state drug benefit management policies. There are certain methodological problems concerning evaluation of state policies. With regard to the issue of internal validity, most prior studies conducted during 1970s-80s used cross-sectional post-only and simple pre-post designs. These designs have been criticized for methodological flaws, especially in an inadequate control for pre-existing differences and time trends which are normally driven by the unmeasured demand and

supply-related factors (Soumerai et al., 1993).

A recent debate on the impact of restrictive drug formularies in managed care has focused on the issue of how to control for the underlying heterogeneity across health maintenance organizations (Ross-degnan and Soumerai, 1996; Horn; 1996). One way to capture the unobserved varying factors in a cross-sectional context is to introduce a time series dimension for every unit of cross-sectional observations. Two recent studies followed this approach by using a pooled cross-sectional time-series analysis of state Medicaid drug expenditures (Moore and Newman, 1993; Ross-Degnan et al., 1993).[1] The present study uses a similar data set that contains both cross-sectional and temporal observations of Medicaid information despite in a different time period.

The use of time-series analysis of Medicaid data in the present study has other advantages, as well. A recent report indicated that growth in prescription drug spending during 1993-1998 was concentrated in a few drug classes and driven by the expenditure per unit dispensed more than the utilization rate. The study also showed an opposite time trend in the market share between the number units dispensed and the dollar sales for the generic drugs (Sherman et al., 1999). Market characteristics of drug products, in particular, are likely to be a nation-wide phenomenon that exhibits variations over time more than across states. The present study operationalizes the temporal variation in the mix of market characteristic of an individual drug and this information is then aggregated into the state level.

All studies to date have treated state restrictive policies as exogenous

[1] Methods and findings for these two studies are described in details in Chapter 2.

(predetermined) variables in a single expenditure/utilization equation. It is possible that state's decision on an implementation of restrictive drug benefit management policies is a response to changes in the expenditures. Differences in drug expenditures across states would bias the estimated effect of a drug cost-containment policy if the policy were simultaneously a function of expenditures. The present study proposes a system of simultaneous equations that are capable of modeling both expenditures and state policy decision.

Most previous study results were based on an analysis of a single-state data set. In fact, several states tend to implement restrictive drug benefit management policies concomitantly. These single-state studies might not be able to differentiate the effect of one policy from another that was concurrently implemented. Furthermore, the Medicaid program is implemented in diverse state environments. The single-state study has a major limitation on generalization of the study results to other states.

The Medicaid Drug Rebate program under OBRA90 was a major recent federal intervention aiming to curb a continual increase in Medicaid drug payments. There were two federally mandated components that changed the way in which a state would reimburse the Medicaid drugs dispensed by retail pharmacies. Beginning on January 1, 1991, the federal government provided Medicaid matching funds to states only for the drugs marketed by a pharmaceutical manufacturer that agreed to pay the Medicaid program according to a specific schedule of rebates. At the same time, states were mandated to cover drug products of the manufacturers that signed the agreements unless the drugs were specified under permissible category exclusions.

A study by Schondelmeyer et al. (1995) revealed the relative changes in Medicaid drug expenditures after the OBRA90 drug rebate program went into effect in 1991. In general, the national Medicaid drug expenditures per Medicaid recipient (adjusted for inflation and net of drug rebates) decreased by 2.9% from 1990 to 1992. However, this temporal change did not occur uniformly through out the country. The study found a discrepancy in both direction and magnitude of the expenditure changes across 49 state Medicaid programs. Twenty-nine states have experienced decreases in Medicaid drug expenditures ranging from 1.0% (in Pennsylvania) to 44.7% (in Wyoming). In contrast, other twenty states found that expenditures increased between 0.8% (in Wisconsin) and 33.5% (in West Virginia) after the OBRA90 legislation.

The federally mandated program was implemented in diverse state-specific contexts with regards to the Medicaid program characteristics and related drug benefit management policies. An attempt to determine the independent effect of each state Medicaid policy will help disentangle the complexity of this empirical issue and help policy makers to understand better the unique contribution of each policy. The studies by Moore and Newman (1993) and by Ross-Degnan et al (1993) have examined the effect of a restrictive drug formulary policy while controlling for the prescription copayment and other drug benefit management policies across states. However, both studies were conducted before OBRA90 went into effect. The present study chooses the years after OBRA90 went into effect to be the study period because this federal intervention may have led states to adapt their own regulatory controls over Medicaid drug benefit management. Recent information on the economic impact of the state restrictions in drug

benefit management policies is limited. The results from this study will be important to policy makers involving in the financing issue of Medicaid drug benefits and the development of Medicare drug policy.

1.3 Study objectives

The primary purpose of this study is to estimate the effect of state restrictions in drug benefit management policies on the per capita Medicaid drug expenditures over the period from 1992 to 1996. The first policy of primary interest is the prescription copayment policy that requires an individual Medicaid enrollee to pay a fixed amount out-of-pocket payment for each prescription filled. The second policy is the prescription cap policy that imposes limits on number of prescriptions that can be reimbursed from Medicaid within a given period. Third, this study focuses on the restrictive formulary policy that places a limit on availability of drug products to be covered by Medicaid programs.

Whether or not the restrictive drug benefit management policies can reduce Medicaid drug expenditures is the research question in this study. The extent to which restrictive policies contribute to cost containment is examined through separate components related to Medicaid drug expenditures. First, variations in the state-level expenditures are captured by a variable representing drug expenditures per Medicaid enrollee. This per enrollee expenditures can be decomposed further into 2 parts associated with drug utilization: (1) propensity to use any drugs; and (2) intensity of expenditures conditional on any use. The first component related to the expenditures per

enrollee is the number of Medicaid drug recipients proportional to total Medicaid enrollees. The second component (intensity) is measured by the expenditures per drug recipient.

In summary, the objectives of this study are:

1. To estimate the effects of state restrictions in drug benefit management policies on Medicaid drug expenditures per enrollee per year;
2. To estimate the effects of state restrictions in drug benefit management policies on intensity of drug expenditures per Medicaid drug recipient per year; and
3. To estimate the effects of state restrictions in drug benefit management policies on the propensity of Medicaid enrollees to use one or more prescriptions in a given year.

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CHAPTER 2

LITERATURE REVIEW

Both published literature and unpublished reports that examine the relationship of Medicaid drug expenditures and state drug benefit management policies are reviewed in this chapter. Each of the three policies of primary interest in this study has been reviewed in a separate section. Research methods used and the major findings from these reviewed studies are presented. The last section in this chapter summarizes major methodological problems that were found in prior studies and the approach used in the present study to minimize these limitations.

2.1 Prescription copayment policy

Findings on impact of Medicaid prescription copayment policy mostly have been based on individual claims data from one-state studies. The designs used in prior studies vary considerably from cross-sectional post-"treatment" surveys and simple pre-post comparisons (with and without a control group) to time-series analysis with a comparison series.

In 1978, Nelson and Quick (1980) conducted a survey of 200 retail pharmacists in South Carolina after the $0.50 prescription copayment policy has been enforced since January 1977. This survey (with 91% response rate) reported 68% of these pharmacists did not waive copayment for patients in order to gain a competitive advantage. Eighty-four percent of the patients did not complain about the copayment requirement. The

study reported a slight increase in an average size of the prescriptions filled by the surveyed pharmacists.

A simple pre-post study of the prescription copayment policy in Alabama reported a decrease in number of drug recipients one month after the $0.50 copayment policy was enacted (Harden, 1976). An increase in number of prescription claims with a small increase in the prescription size was also found.

In California, a concurrent copayment policy of $0.50 per prescription and $1.00 per physician visit was enacted in July 1972. Brian and Gibbens (1974) conducted a pre-post comparison between Medicaid enrollees who were required to pay out-of-pocket copayments and a comparison group without copayments. Data from the 12-month period showed a decrease in both number of prescriptions and physician visits in the copayment group. Reanalysis of the above study found an observed decline in use of preventive care and an increase in hospitalization in the copayment group (Roemer et al., 1975).

Two other studies have drawn conclusions by comparing time-series data in South Carolina, a state with the $0.50 copayment policy, to the data in Tennessee, which had no prescription copayment policy. One study found a greater decrease in monthly prescriptions per recipient in South Carolina during the three-year period after the copayment policy was implemented (Nelson et al., 1984). Neither state showed an increase in the average prescription size. The other study reported a short-term drop in monthly drug expenditures per enrollee and a long-term decline in expenditure trends for certain drug classes in South Carolina, the copayment state (Reeder and Nelson, 1985).

Stuart and Zacker (1999) used a subset of national representative survey data on payment sources and utilization patterns of prescribed drugs in 1992. The study sample consists of 1,302 elderly and disabled persons who had dual Medicare-Medicaid eligibility in thirty-nine states. Fifty-two percent of the respondents resided in twenty-one states with copayment policy. The study found that Medicaid enrollees in the copay states reported filling five fewer prescriptions annually than their counterparts in the eighteen non-copay states. Based on regression analyses that controlled for prescription cap policy, the copayment policy was associated with a reduction in the filled prescriptions by 15.5%. Major discrepancy between the copay and the non-copay states was found in the percentage of Medicaid enrollees reporting any drug use rather than in the prescription counts from Medicaid drug recipients. Another interesting finding is that pharmacies in the copay states failed to collect the full amounts of copayments in almost 30% of the prescriptions. Interestingly, the magnitude of this uncollectible proportion of the prescription copayments is comparable to the findings from the previous study by Nelson and Quick (1980).

2.2 Prescription cap policy

A recent time-series analysis of Medicaid claims data in Georgia was conducted by Martin et al. (1996). The study showed a decrease in the number of claimed prescriptions per recipient during the six-month period after the monthly prescription limits were tightened from 6 to 5 prescriptions. There was a temporary increase in the per recipient average of monthly out-of-pocket prescriptions dispensed by the surveyed

pharmacies. For certain drug classes, the monthly average of all-payer prescriptions per recipient decreased over time.

Soumerai et al. (1987) used a well-designed time-series analysis to compare Medicaid drug utilization and expenditures in New Hampshire, a state with a prescription cap policy followed by a replacement by a copayment policy, to New Jersey, which imposed neither restrictions. This study found a 46% decrease in the number of prescriptions per recipient for the multiple-drug user subgroup and a 17% decrease for all other drug recipients during the eleven-month period under the prescription cap policy. Then, the average prescriptions per drug recipient in both subgroups increased toward the pre-limit level during the following seventeen months under the copayment policy. In the comparison state, there were very low month-to-month variations in the Medicaid drug utilization. The same study also reported a 38% decrease in Medicaid drug expenditures for the multiple-drug users and a 19% decrease for the rest of drug recipients during the prescription cap period. However, expenditures in the multiple-drug user subgroup showed an increasing trend toward the pre-limit level after the copayment policy went into effect.

The second study conducted by Soumerai et al. (1991) in the same states focused on the Medicaid elderly who were multiple-drug users. This study showed a 35% decrease in the monthly doses of core drugs per recipient during the prescription cap period, then the use of core drugs returned to almost the pre-limit level after the following copayment policy.

2.3 Restrictive drug formulary policy

Restriction on drugs that are covered by Medicaid programs due to state formularies has been an issue of interest since 1970s. Three prior studies described various degrees of the delays and lack of formulary approval for newly FDA-approved drug products during 1970 to 1985 (Schweitzer et al., 1985; Grabowski, 1988; and Grabowski et al., 1992). As indicated by fractional time lags and rates of the formulary approval for the new drug products, states that implemented restrictive drug formularies showed a varying degree of the formulary restriction.

Prior studies of association between restrictive formularies and drug utilization and expenditures in Medicaid program can be divided into 2 major groups based on units of analysis.

2.3.1 Patient-level data analysis

All studies using patient-level data in Louisiana, Michigan, and New Jersey reported the decreases in number of prescriptions and recipients of the drugs that were used for minor illnesses and drugs with questionable efficacy or potential misuse in these restrictive formulary states (Hefner, 1979; Smith and McKercher, 1984; and Soumerai et al., 1990). In contrast, studies in Mississippi, Wisconsin, and New Jersey found increased use of drug products that were potential substitutes of the formulary-excluded drugs (Smith and MacLayton, 1977; Kreling et al., 1989; and Soumerai et al., 1990). Hefner (1979) also reported an increase in hospitalization, a potential unintended second-

order effect in Louisiana. In Michigan, a study by Smith and McKercher (1984) found a cost-shifting effect from Medicaid payments to the patient out-of-pocket payments.

The potentially counter-acting effect from the utilization of the substituted alternatives may lead to diverse findings across studies with regard to direction of the effect on the overall drug expenditures. These include a significant decrease (Hefner, 1979), a non-significant change (Soumerai et al., 1990), and a significant increase (Smith and MacLayton, 1977) in Medicaid drug expenditures.

Two other studies have analyzed the expenditure data in Texas, a control state with an open drug formulary, in comparison with other states that implemented the restrictive formulary. The study in Louisiana found a decrease in drug expenditures but a greater increase in other health care expenditures (Hefner, 1980). The other study in California reported relatively higher amount of both per recipient drug expenditures and Medicaid program expenditures (Sudovar and Rein, 1978).

2.3.2 State-level data analysis

The second group of Medicaid drug formulary studies has analyzed the aggregate expenditures across states. Nearly all of them retrieved the data on the restrictive formulary policy from the annual reports published by National Pharmaceutical Council (NPC). One of them showed inconclusive findings (Hammel, 1972). The other three reported that the presence of a restrictive drug formulary policy was not associated with the variation in per recipient drug expenditures across states (Taubman, 1974; Smith and

Simmons, 1982; and Schweitzer et al., 1985). All of these studies relied on cross-sectional data after a new restrictive policy was implemented.

Two recent studies used pooled cross-sectional time-series data sets from multi-states over several time periods and regression analyses to separate the effect of restrictive drug formularies from other drug benefit management restrictions that have been implemented concurrently in certain states. The first study conducted by Moore and Newman (1993) analyzed the panel data of Medicaid expenditures from all states, except Arizona, Alaska, and Wyoming during 1985-1989. The study used the annual drug expenditures per capita rather than per Medicaid-eligible individual or per drug recipient as the dependent variable. The restrictive drug formulary, which is the policy of primary interest, was defined by a binary variable representing a presence vs. an absence of the policy in a state as reported by the NPC. Other control variables included three additional state drug policies (prescription copayment amount, number of state MAC drugs, and dispensing fee) and regulatory constraints in other Medicaid services, Medicaid population characteristics, and economic factors (per capita income, unemployment rate, and federal Medicaid matching rate). The study results revealed that a 13.4% decrease in drug expenditure was associated with the presence of Medicaid drug formularies in certain states. The study also reported an evidence of regression toward the state mean for both drug and total healthcare expenditures over time in the states that enacted the restrictive drug formulary sometimes after the provision of Medicaid drug benefits.

The second study by Ross-Degnan et al. (1993) pooled the state Medicaid data from a relatively longer period during 1980-1990. As in the previous study, Ross-Degnan et al. (1993) used a dummy variable representing the presence of a restrictive drug formulary as reported by NPC as the policy variable of primary interest. However, the study used some different measures of Medicaid drug policies including the presence of prescription copayments, prescription cap, prior authorization, and number of excluded drug categories as the control variables. The study estimated the effects on the expenditures per recipient in two sets of state panels. Data from the District of Columbia and all states except Arizona revealed the independent relationship between the presence of the restrictive drug formulary, in general with a decrease in drug expenditures by 10.2%. For a subset of 12 states with an apparent change in formulary status during the observation period, the study also added a set of state dummy variables in the model to control for the unobserved differences among the states in the state-specific average variations over time. This second set of data showed that an adoption of the restrictive formulary during 1980-1990 would decrease drug expenditures by 7.0%.

Both studies have shown non-significant association between the restrictive drug formulary and Medicaid total health care expenditures. Moore and Newman (1993) concluded that this finding was due primarily to significant increases in physician service and inpatient hospital expenditures by 28.7 and 39.1%, respectively. However, Ross-Degnan et al. (1993) cited random error and corresponding lack of sensitivity in the total health care expenditures due to the small fraction of drug expenditures as the major causes for the no association.

2.3.3 Non-restrictive drug formulary

Previous studies on the generous drug benefit management policies are quite limited. Before OBRA90 was enacted, two studies on the effects of expansion of drug coverage in Medicaid formularies have been conducted. The first study used a pre-post comparison without a comparison group to detect the effects of adding several newly marketed anti-infective drugs into the Illinois' drug formulary (Dranove, 1989). The study found a non-significant decrease in outpatient hospital visits among non-elderly beneficiaries who had infectious diseases. However, both anti-infective drug and outpatient visit expenditures have increased by 6%.

The second study used repeated measures to detect effects of expanding South Carolina's drug formulary for 12,139 non-elderly Medicaid enrollees (Kozma et al., 1990). The study reported increases in number of prescriptions, physician visits, and outpatient hospital visits per person but a decrease in inpatient hospital admissions.

After the OBRA90 became effective, Walser et al. (1996) surveyed opinions from two separate panels of physicians with regards to the potential therapeutic benefits of the eighteen top-200 drugs with increased coverage due to the open access provisions. These eighteen 'open-access' drugs were defined as the drugs that, previously in 1989, were not covered by at least 10% of the Medicaid formularies (in 49 states) but were covered later by at least 4 states in 1992. The study showed that there were only 4 drugs that were mutually agreed by the panels as the drugs with additional clinical advantage or net therapeutic benefits.

The same study also revealed that, in states that previously had imposed restrictive formularies, the average number of drugs covered after the implementation of OBRA90 increased from 169.3 to 186.3 drugs, compared with the stable coverage of 196 drugs in the states without restricted formularies. Also, average number of prior authorization requirements, imposed by the former group increased from 1.4 to 3.8 drugs, compared with an increase from 0.7 to 1.4 drugs in the latter group.

2.4 Summary

Prescription copayment and prescription cap policies have been found to reduce the utilization of, and expenditures for, Medicaid drugs. However, there was some variation in the magnitude of effect upon utilization. Most of the previous studies of these two policies have been conducted on data from a single state. These studies typically have not included other states for comparison purposes. Studies of the impact of restrictive drug formulary policies have sometimes used individual patient-level data, while other studies have used state-wide aggregate data. Published studies of the impact of restrictive drug formularies reached diverse conclusions regarding the effect on overall drug expenditures. Apart from the potential substitution effect of one drug for another drug (therapeutic substitution) or substitution of other health care services for drugs, much of the difference in these findings resulted from inadequate research designs and analytical methods. To attribute any observed differences in Medicaid expenditures to the change in a specific Medicaid policy, one would need to assume that no other determinants of the drug expenditure level have systematically changed. Such an

assumption becomes quite vulnerable as the time period of observation becomes longer. Only two studies (Soumerai et al. 1987, 1991) using patient-level data relied on a well-designed time-series with a comparison state.

Also two studies using state-level data (Moore and Newman, 1993; Ross-Degnan et al, 1993) used pooled-regression analyses over a multiple-year period. Although both of these studies used state panel data to capture between-state variation while controlling for temporal variation within a state, neither study addressed the issue of endogeneity of state policy variables. The study by Moore and Newman (1993) directly added state-wide economic and employment factors as control variables to the Medicaid expenditure equation. State variations in the restrictive drug formulary policies in both state-level studies used the very crude binary terminology (yes or no) as reported in annual National Pharmaceutical Council publications. When this binary variable was assessed by Ross-Degnan et al. (1993) in 1989, 13% of the states that covered fewer than 195 of the top 200 selling drug products were labeled (by the NPC annual reports) as not having restrictive drug formularies.

The present study introduces two methodological improvements over the previous studies of Medicaid drug benefit management policies. First, the variable representing a state's restrictive drug formulary policy is defined in a more quantitative manner. Rather than using a binary variable that defines the presence vs. absence of a restrictive formulary policy (as reported by the NPC survey), this study determined the proportion of all drug products that were restricted by a state's drug formulary. This variable was operationalized to determine the proportion of drug products not reimbursed by the state

among all drug products that could have been used for the same therapeutic indication. Second, this study formally used instrumental variables (such as state-wide economic and political factors) to adjust the predicted impact of drug benefit management policies on Medicaid drug expenditures per capita.

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CHAPTER 3

THEORETICAL MODEL AND RESEARCH HYPOTHESIS

The first section in this chapter describes a theory that can be used to explain drug utilization behavior of a Medicaid eligible individual as a response to the restrictions in Medicaid drug benefit management. The theoretical model is based on the Demand-for-Health model developed by Michael Grossman (1972). The second section addressed research hypotheses that are supported by the theoretical backgrounds from the first section.

3.1 Theoretical model

Whether or not the drug utilization-targeted restrictions imposed by state Medicaid agencies can reduce Medicaid drug expenditures is the research question in this study. Decision-makers involving in this issue are at two levels. First, an eligible individual who is the potential user of Medicaid drugs has to decide whether to fill the prescriptions received. Second, a state Medicaid agency makes a decision on whether to implement the restrictive drug benefit management policies and how much the degree of the restrictions would be.

The decision of the Medicaid enrollee to fill a prescription is assumed to be influenced by his/her underlying health care need and the state drug benefit management policies. The product of the individual's amount of drug use and the Medicaid payment rate per unit of the use aggregated over all drug recipients would determine the total drug

expenditures in a given state. At the same time, the decision of the state Medicaid agency to impose restrictions on drug benefit management can be driven by a motivation to reduce excessive utilization experienced through the unusually high Medicaid expenditures. Relationships between Medicaid drug expenditures and the drug benefit management policies can be viewed as a recursive model where the utilization/expenditure variables and the policy variables are simultaneously determined.

3.1.1 Drug expenditure components

To examine the effect of the utilization-targeted policies independent of the price-related policies, Medicaid drug expenditures are to be decomposed into related pricing and utilization components. Then, the primary factors that can influence the payment rate per prescription can be delineated and controlled in the estimation model.

Medicaid payment rate

Drug expenditure equals the product between total amount of drug use and payment rate per unit of use. State variations in Medicaid costs per unit of use can be captured by Medicaid payment rate per prescription, which is a combination between drug ingredient cost and dispensing fee. An increase in each of these unit cost components would result in increases in both per recipient expenditures and per enrollee expenditures.

The allowable ingredient cost is based primarily on market characteristics of drug products. Medicaid payment for several multi-source drug products is capped at the maximum allowable costs (MAC), which is comparable to the prevailing prices of

generic drugs. Several states have implemented a variety of generic substitution policies. However, health care providers can avoid potential generic substitution by prescribing single-source drugs and multi-source drugs with brand medically necessary.

Estimated acquisition costs (EAC) for single-source drugs, multi-source drugs prescribed with brand medically necessary, and non-MAC drug products are specified as a fraction of average wholesale price (AWP), which is varied across states. An increase in generic substitution rate and a decrease in single-source drug fill rate will help decrease the drug ingredient cost per prescription.

The following factors were included as covariates in the estimation equation to control for variations in the average payment per prescription: (1) drug ingredient cost allowance expressed as the fraction of AWP (e.g., 0.90 when pharmacies are allowed AWP – 10% as the allowable drug ingredient cost); (2) maximum dispensing fee amount per prescription allowed by the state's 'lower of' formula for determining prescription payment amount; and (3) mix of prescriptions by patent status reported as single-source drug fill rate (i.e., the proportion of prescriptions for a chemical-equivalent drug that were for single source, patent-protected products); and (4) the generic substitution rate measured as the proportion of off-patent prescriptions that were dispensed with a lower-cost generic products.

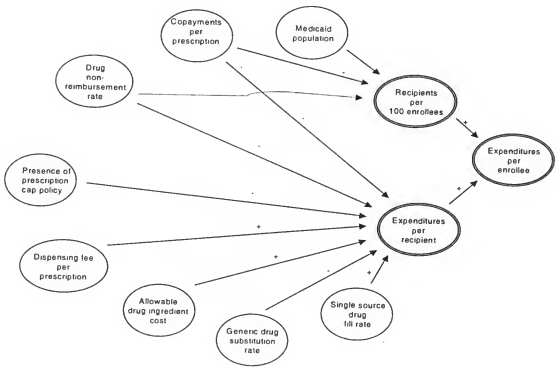
Medicaid drug utilization

The utilization components of Medicaid drugs can be decomposed further into two deterministic parts. The first part differentiates those who have any drug use in a given period from those who have not. In this study, the propensity to use any drugs is

estimated from the fraction of Medicaid enrollees whose prescriptions were reimbursed by Medicaid at least once in a year. The second part models intensity of the use conditional on any use. This can be derived from the total units of use per Medicaid drug recipient. The anticipated relationship between restrictive drug benefit management policies and each component of drug utilization and expenditures are addressed further in details. Figure 3.1 illustrates the inter-relationship between Medicaid drug expenditure components and related factors.

Figure 3.1

Relationship between drug expenditures and related factors



+ : Positive relationship; - : Negative relationship

A Medicaid drug recipient normally does not have to pay for a prescription received and filled. A pharmacy is reimbursed for the filled prescription according to the payment rate allowed by state Medicaid agency. An individual Medicaid enrollee is assumed to decide whether or not to fill a prescription he/she received if the prescription requires out-of-pocket copayment or is beyond reimbursable limit, or if the drug prescribed is not covered by drug formulary.

3.1.2 Demand-for-Health Model

The patient's demand for prescription drugs is considered as the derived demand for a medical input to restore an individual's health. Health, itself is perceived in both investment and consumption aspects based on the Demand-for-Health Model, which was adapted from the Human Capital Theory by Michael Grossman in 1972.

According to the pure investment aspect, health is desired because it increases the number of healthy days available to work and thus to earn incomes. People invest in health by using their income to purchase medical inputs including prescription drugs and other medical care from the market and by spending their own time on health-improving efforts.

An investment in health can be derived as a production function for health as

$$H = f(M, T, H^0) \tag{3.1}$$

where H is the stock of health as the desired output

M is the quantity of medical inputs like prescription drugs purchasing from the market

T is the individual's leisure time allocated specifically for health investment

H^0 is the endowed baseline health status.

Like all other typical production functions, the marginal productivity of each input on health representing by the first-order partial derivatives are positive ($f_M > 0, f_T > 0, f_{H^0} > 0$). An increase in medical input or time devoted to health-improving efforts would improve health. However, such improvement is at a decreasing rate with respect to the increase of the corresponding input. Hence, their second-order partial derivatives are all negative ($f_{MM} < 0, f_{TT} < 0, f_{H^0H^0} < 0$).

The endowed H^0 is considered to affect the marginal productivity of the inputs M and T such that f_M and f_T for the people with lower H^0 is greater than in their higher H^0 counterparts. Hence, the cross-partial derivatives are negative ($f_{MH}{}^0 < 0$ and $f_{TH}{}^0 < 0$).

People as producers also use their incomes to purchase other market inputs and spend their own time in order to produce goods/services that increase the individual's satisfaction and enjoyment of life. These goods/services may represent a composite of all other things that people do with their leisure time. Under the pure investment aspect, health is valued only for what it can produce. Thus, the objective is to choose the optimum investment in the stock of health (H^*) under a constraint of total costs of medical inputs and available leisure time, given the optimum production of all other things.

The objective function for an investment in health, subject to the cost constraint, can be formalized as

$$\underset{M,T}{Max}\, H = f(M,T,H^0) \text{ subject to } C^* = pM + T \tag{3.2}$$

where p is the unit price of medical inputs like prescription drugs, given that the unit price of leisure time is normalized to 1

C^* is the total costs of medical inputs and time that are available after taking account of the optimum production of all other things.

The above cost-constrained maximization problem of health production can be rewritten as the cost minimization problem subject to the production technology constraint.

This is equivalent to

$$\underset{M,T}{Min}\, pM + T \text{ subject to } f(M,T,H^0) = H^* \tag{3.3}$$

That $\frac{\partial M^*}{\partial p} < 0$ would satisfy the solution for the optimum choices of M^* and T^* in the above problem. This means that the demand for prescription drugs (M), in order to produce the optimum amounts of health stock under the cost constraint condition, should fall as the corresponding prescription price people have to pay (p) increases. If the time (T) is a perfect substitute of prescription drugs and other medical inputs, then people will try to invest in health with a greater input of time (T).

The second perception of heath is that health also has its own intrinsic value as in other consumption goods that make people feel better. Under the consumption aspect, a consumer would like to maximize his/her utility derived from the consumption of health and other goods under his/her budget constraint.

Given that X represents a composite of all other consumption goods, the budget-constrained utility maximization problem for a two-good consumption bundle of H and X can be formalized as

$$MaxU(H,X) \text{ subject to } I^* \tag{3.4}$$

where I^* is the individual's total income.

The total income (I^*) comes from 2 major sources: non-wage income like returns to financial investments and earned income from working. Given that T^0 is the leisure time (in hours) spent for health investment and doing all other things, and w is the hourly wage rate that a consumer is able to earn by using the available working time[1]; the total possible earned income is $24w$ and the opportunity time cost spent for health investment and all other things is wT^0. Hence, the earned income is $w(24\text{-}T^0)$.

Given that Y is non-wage income, total income can be derived by

$$I^* = Y + w(24 - T^0) \tag{3.5}$$

The consumer's total income (I^*) will be used for an investment in health (H) as a function of $f(M, T, H^0)$ by purchasing market medical inputs like prescription drugs (M) and for purchasing other consumption bundles (X).

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[1] According to the labor-leisure choice model, people will partition the 24 hours of their endowed time for working hours and leisure by equating their wage rate and their marginal utility of income *vs* leisure (Silberberg, 1990). The optimum leisure time (T^0) depends on the wage rate (w) and the utility function of income-leisure. An increase in wage rate has a substitution effect that motivates people to work longer and the opposite income effect that makes the people feel richer, and thus want more leisure. If the effects canceled out completely, T^0 would not be affected by w and can be treated exogenously.

Given that the unit price of X is normalized to 1, the total income is equal to the total outlay according to the following relationship

$$I^* = pM + X \tag{3.6}$$

To solve for the optimum choice of M^*, T^*, and X^*, the above constrained maximization problem can be rewritten as

$$\underset{M,T,X}{Max} U[f(M,T,H^0),X] \text{ subject to } Y + w(24 - T^0) = pM + X \tag{3.7}$$

There is another concern about time cost in obtaining medical inputs from the market like waiting time, traveling time, and searching time which are associated with the provider accessibility issue. Given τ as the time (in hours) spent in order to receive the medical inputs, the original budget constraint can be expanded to

$$Y + w(24 - T^0) = (w\tau + p)M + X \tag{3.8}$$

Hence, the constrained maximization problem can be revised as

$$\underset{M,T,X}{Max} U[f(M,T,H^0),X] \text{ subject to } Y + w(24 - T^0) = (w\tau + p)M + X \tag{3.9}$$

By multiplying the original budget constraint function with a Lagrange multiplier (λ), the same maximization problem can be formalized by a new Lagrangian function (L) as

$$\underset{M,T,X,\lambda}{Max} L = U[f(M,T,H^0),X] + \lambda\{Y + w(24 - T^0) - (w\tau + p)M - X\} \tag{3.10}$$

In order to determine the optimum levels of choice variables: M, T, X, and λ according to the above objective function, the following conditions have to be satisfied.

1. The first-order necessary conditions are

$$L_M = U_1 f_M - \lambda(w\tau + p) = 0, \tag{3.11}$$

$$L_T = U_1 f_T - \lambda w = 0, \tag{3.12}$$

$$L_X = U_2 - \lambda = 0, \text{ and} \tag{3.13}$$

$$L_\lambda = Y + w(24 - T^0) - (w\tau + p)M - X = 0 \tag{3.14}$$

2. The second-order sufficient condition can be expressed by a determinant of the matrix for the cross-partial derivatives of L as

$$\begin{vmatrix} L_{MM} & L_{MT} & L_{MX} & L_{M\lambda} \\ L_{TM} & L_{TT} & L_{TX} & L_{T\lambda} \\ L_{XM} & L_{XT} & L_{XX} & L_{X\lambda} \\ L_{\lambda M} & L_{\lambda T} & L_{\lambda X} & L_{\lambda\lambda} \end{vmatrix}$$

This can be transformed into a determinant of the bordered Hessian matrix ($|H|$) as

$$\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{12} f_T & U_{22} & -1 \\ -(w\tau + p) & -w & -1 & 0 \end{vmatrix}$$

The sign for $|H|$ and all border-preserving principal minors of $|H|$ in order to satisfy the second-order condition for this constrained maximization problem is determined by $(-1)^k$, where k is the order of the corresponding determinants.

In this case, $|H|$ is the 3rd-order determinant of the bordered Hessian matrix. Hence, $|H|$ has a negative sign or $|H| < 0$. Similarly, all three principal minors of $|H|$ with the order of 2 will have positive signs.

In order to hypothesize the qualitative effects or the direction of changes on the demand for prescription drugs with respect to each exogenous variable like prescription

price and time cost in obtaining prescription drugs, a mathematical logical simulation called comparative statics will be developed further.

First, all first-order partial derivatives of L will be taken for total differentials with respect to all choice variables and all exogenous variables as follows.

$$dL_M = (U_1 f_{MM} + U_{11} f_M f_M)dM + (U_1 f_{MT} + U_{11} f_M f_T)dT + (U_1 f_{MH^0} + U_{11} f_M f_{H^0})dH^0 + U_{12} f_M dX - (w\tau + p)d\lambda - (\lambda dp + \lambda w d\tau + \lambda\tau dw + 0dY) \quad (3.15)$$

$$dL_T = (U_1 f_{MT} + U_{11} f_M f_T)dM + (U_1 f_{TT} + U_{11} f_T f_T)dT + (U_1 f_{TH^0} + U_{11} f_T f_{H^0})dH^0 + U_{12} f_T dX - wd\lambda - (0dp + 0d\tau + \lambda dw + 0dY) \quad (3.16)$$

$$dL_X = U_{12} f_M dM + U_{12} f_T dT + U_{12} f_{H^0} dH^0 + U_{22} dX - 1d\lambda - (0dp + 0d\tau + 0dw + 0dY) \quad (3.17)$$

$$dL_\lambda = -(w\tau + p)dM - wdT + 0dH^0 - 1dX + 0d\lambda - [M(dp + wd\tau) - (24 - T^0 - \tau M)dw - 1dY] \quad (3.18)$$

The above total differentials are, then, equate to zero. In matrix expression, this is equivalent to

$$\begin{pmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{12} f_T & U_{22} & -1 \\ -(w\tau + p) & -w & -1 & 0 \end{pmatrix} \begin{pmatrix} dM \\ dT \\ dX \\ d\lambda \end{pmatrix}$$

$$= \begin{pmatrix} U_1 f_{MH^0} + U_{11} f_M f_{H^0} & \lambda & \lambda w & \lambda\tau & 0 \\ U_1 f_{TH^0} + U_{11} f_T f_{H^0} & 0 & 0 & \lambda & 0 \\ U_{12} f_{H^0} & 0 & 0 & 0 & 0 \\ 0 & M & wM & -(24 - T^0 - \tau M) & -1 \end{pmatrix} \begin{pmatrix} dH^0 \\ dp \\ d\tau \\ dw \\ dY \end{pmatrix} \quad (3.19)$$

The development of comparative statics for the variables of interest is illustrated

in Appendix A.

From the comparative statics in Appendix A, the optimum consumption of prescription drugs and the optimum amount of time spending for health-improving efforts can be derived as functions of

$$M^* = f(H^0, Y, p, \tau, w) \tag{3.20}$$

$$T^* = f(H^0, Y, p, \tau, w) \tag{3.21}$$

Relationship between the choice variables (M^*, T^*) and each predetermined variable is as follows:

$$\frac{dM^*}{dH^0} \gtrless 0, \frac{dM^*}{dY} > 0, \frac{dM^*}{dp} < 0, \frac{dM^*}{d\tau} < 0, \text{ and } \frac{dM^*}{dw} \gtrless 0, \text{ and}$$

$$\frac{dT^*}{dH^0} \gtrless 0, \frac{dT^*}{dY} > 0, \frac{dT^*}{dp} > 0, \frac{dT^*}{d\tau} > 0, \text{ and } \frac{dT^*}{dw} \gtrless 0.$$

In summary, the above logical exposition suggests that the demand for prescription drugs (M^*) would fall and be substituted by a greater input of the time spent for health-improving efforts (T^*) as a response of

(1) a decrease in the individual's income (Y),

(2) an increase in the prescription price (p) people have to pay for, and

(3) an increase in time in obtaining the prescriptions and having the prescriptions filled (τ).[2]

[2] People also use other medical care in addition to prescription drugs in the production of health. For ease of exposition, these drug alternatives are implicitly represented by M as the composite medical inputs. Effects on the substituted medical cares will have the same direction as T^*.

In summary, based on Grossman's Demand-for-Health Model (1972), the demand for medical care is expected to decrease (with potential substitution of leisure time spent in health-improving efforts) as a consequence of an increase in effective price of medical care and time cost of obtained the care.

3.2 Research hypothesis

Patient cost-sharing required by health insurance plans would result in an increase in the effective price perceived by an insured person. Prior empirical evidence suggests that increased cost-sharing leads to decreased demand for medical services of the insured population (Rice and Morrisson, 1994). Data from the Rand Health Insurance Experiment, a randomized controlled trial, showed that the cost-sharing response for prescription drugs was similar to the response for all ambulatory medical services (Leibowitz et al., 1985). The study reported significantly fewer drug expenditures per capita in the health plans that required patient cost-sharing compared with the free plan. Much of the expenditure difference was related to the quantity of claimed prescriptions per capita rather than average payment rates. Even though coinsurance payments depend on costs of the reimbursed drugs, the study did not find significant substitution of the cheaper generic drugs for the brand drugs in the plans with coinsurance policies.

The effect of prescription copayments on drug utilization in the Medicaid population may be stronger than in the general population because the seemingly minor amount of out-of-pocket copayments may constitute a significant financial contribution for this low-income population. With regard to the effect on drug utilization components,

a copayment policy can reduce the likelihood that a Medicaid enrollee would fill a prescription, especially for the drug product they deem unnecessary. Hypothesis 1 (H_1) therefore proposes that a state that has a greater amount of copayments per prescription will have a lower number of Medicaid drug recipients in proportion to the total number of Medicaid enrollees. The first hypothesis implies the effect of prescription copayments on the propensity to use one or more prescriptions at the state level.

Second, the copayment policy can reduce the intensity of use among Medicaid drug users. Hypothesis 2 (H_2) therefore proposes that a state that has a greater amount of copayment will have a lower drug expenditure per Medicaid drug recipient. As a consequence, a state that requires a higher amount of copayment will bear a lower Medicaid drug expenditure per Medicaid enrollee as proposed in H_3.

A prescription for most drug products, especially maintenance medication usually contains one-month supply of each drug. A prescription cap policy that limits number of the refilled prescriptions not less than 5 times within 6 months would make not much different. All states that enacted the prescription refill limit policy have the limits not less than the above level. Hence, this study focuses only when the new prescriptions are capped.

Limits on the reimbursable quantity of new prescriptions within a given period would have a direct effect on number of drug entities that can be reimbursed rather than the quantities supplied for each drug product. This policy is likely to affect Medicaid enrollees who are the users of multiple drugs by decreasing intensity of the use. A state that implements the prescription cap policy will have a lower drug expenditure per drug

recipient as stated in H_4. As a consequence, the per enrollee expenditures will be relatively lower in a state with the prescription cap policy (H_5).

A restrictive drug formulary that limits Medicaid coverage for certain drugs will reduce the utilization of formulary-excluded drugs unless Medicaid recipients pay out-of-pocket for these drugs. However, the formulary-approved drugs can be substituted for the excluded drugs in the same therapeutic indications. Hence, the restrictive drug formulary would not decrease propensity to use *any* drugs significantly unless there were no alternatives available or the substitution effect was very weak. It is unlikely that states will exclude all drugs that are available in a given therapeutic class. Exclusion of certain drugs from Medicaid reimbursement by a restrictive formulary would not be expected to have a substantial effect on the number of drug recipients proportional to the total number of Medicaid enrollees (H_6).

A state that imposes more coverage restrictions through a drug formulary or prior authorization will be expected to have a lower drug expenditure per drug recipient (H_7) and a lower drug expenditure per Medicaid enrollee (H_8).

In summary, these are the research hypotheses indicating the direction of the expected effect for each state restriction in drug benefit management policy:

H_1: A state that uses a higher amount of copayment per prescription will have fewer drug recipients as a proportion of total number of Medicaid enrollees;

H_2: A state that uses a higher amount of copayment per prescription will have a lower Medicaid drug expenditure per drug recipient;

H_3: A state that uses a higher amount of copayment per prescription will have a

lower Medicaid drug expenditure per Medicaid enrollee;

H_4: A state that places a limit on the number of prescriptions covered per month per drug recipient will have a lower Medicaid drug expenditure per drug recipient;

H_5: A state that places a limit on the number of prescriptions covered per month per drug recipient will have a lower Medicaid drug expenditure per Medicaid enrollee;

H_6: The proportion of Medicaid enrollees who receive one or more prescriptions in a given year is not related to the proportion of drugs restricted (by formulary or prior authorization) in a state;

H_7: A state that has a higher proportion of drugs restricted (by formulary or prior authorization) will have a lower Medicaid drug expenditure per drug recipient;

H_8: A state that has a higher proportion of drugs restricted (by formulary or prior authorization) will have a lower Medicaid drug expenditure per Medicaid enrollee.

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CHAPTER 4

METHODOLOGY

The first section in this chapter presents the econometric approach that can be used to answer the research questions raised in Chapter 1. Based on nature of the data used by this study, the cross-sectional observations on the state-level variables are combined with temporal observations over the five-year periods. Pooled cross-sectional time-series regression is the primary candidate for estimation models. In addition, a system of simultaneous equations is proposed in this study to deal with the potential problem of endogeneity of the state Medicaid policy variables.

The second section addresses the issue of measurement of variables to be used in the three equations related to Medicaid drug expenditures. The dependent variable in the first equation is the expenditures per enrollees. The second equation uses the expenditures per recipient as the dependent variable. The third equation is estimated on the drug recipients per 100 enrollees. Variables to be specified in the estimation models are derived from the theoretical background that is explained in the previous chapter. Data sources and operational definitions of the variables are described in this second section. The third section proposes the variables that can be used as the instruments for endogenous state Medicaid policies. The theoretical basis for the endogenous Medicaid policy is described in the last subsections in order to support the selection of the policy determinant variables.

4.1 Data analysis

4.1.1 Pooled cross-sectional time-series data

A pooled cross-sectional time-series data set containing longitudinal observation of a panel of variables is chosen for this study. Panel data offer several advantages. First, panel data can be used to answer research questions that cannot be addressed by conventional time-series or cross-sectional data. For example, a time-series of national aggregate data cannot provide an efficient estimate of the effect of a policy variable that exhibits multicollinearity between the current and lag values. It is also difficult to make inference about impacts of the temporal change in a policy from a cross-sectional data set.

Second, cross-sectional or simple pre-post comparisons cannot reduce bias from an unobserved time-varying factor that is correlated with both the policy variables of interest and the dependent variables. By pooling cross-sectional units of observation over several time periods, information from both between-unit and within-unit variations can be examined.

Statistically, panel data offer an approach to the problem of a limited number of state level observations. An increase in degrees of freedom as a result of the combination of cross-sectional and temporal observations helps improving statistical significance level and, consequently, efficiency of parameter estimates in the well-specified model.

This study combines data from 49 cross-sectional units of Medicaid jurisdictions with 5 temporal observations of the federal fiscal years: 1992 – 1996. This results in a

single set of panel data consisting of 245 total state-years.

The regression model for this pooled cross-sectional time-series data set can be represented as

$$Y_{it} = \sum_{k=1}^{K} \beta_k X_{itk} + U_{it} \qquad (4.1)$$

where Y_{it} is the dependent variable observed in state i at year t

(i = states 1, 2, 3, …, 49; and t = years 1992, 1993, 1994, 1995, 1996)

X_{it} is a set of K explanatory variables including an intercept (X=1)

U_{it} is the error term

$\beta, \sigma^2_{U_{it}}$ are the parameters to be estimated

In this pooled model, it is assumed that the regression coefficients (β) are constant across both cross-sectional and temporal subsets of the data. Specifically, this study assumes that the effects of policies of interest do not vary significantly across 49 state time-series.

The assumption that the policy effects stay constant across 5 years of state panels can be tested by using Chow Test for the appropriateness of pooling sub-samples (Greene, 1997). F-statistics from this test indicate the relative magnitude of the difference in mean square errors between the pooled regression and sum of the separate cross-sectional regressions. Statistical non-significance of the test suggests that pooling the data is appropriate and there is no need for an inclusion of the interaction terms between the policy variable and time period in the pooled model.

4.1.2 Selection of estimation models

This sub-section provides justification on estimation techniques that are well suited for the available data. The candidate estimators include ordinary least squares (OLS) estimate, least squares dummy variable (LSDV) or fixed-effect estimate, and generalized least squares (GLS) or random effect estimate.

Ordinary least squares estimate

The estimation method for the pooled model by ordinary least squares (OLS) requires the following assumptions of classical linear regression (Kennedy, 1998).

1. Dependent variable is a linear function of explanatory variables plus an error term
2. The expected value of the error term is zero
3. Distribution of the error term has identical variance and is independent from each other
4. Observation on the explanatory variables is considered fixed in repeated samples
5. Number of observations is greater than number of explanatory variables and there are no exact linear relationships among the explanatory variables

This study begins with OLS regression for the cross-sectional data in each of the five years. Each OLS estimate is tested for non-normality (Shapiro and Wilk, 1965; D'Agostino, et al., 1990), non-linearity and omitted variables (Ramsey, 1969), and heteroscedasticity (Cook and Weisberg, 1983, Park, 1966; Glejser, 1969).

In a pooled time-series model, it might be reasonable to assume independent

distribution of the error term across states. In a given state, however, the error term is unlikely to distribute independently from each other over time. To choose the most suitable model for fitting the data, a reasonable assumption of the error term distribution is a primary concern.

Fixed effect or within-effect estimate

One of the estimators that can be applied to the pooled regression model is fixed effect or within-unit estimate. This estimation model introduces a set of dummy variables representing (1) the effects of an unobserved factor that are specific to cross-sectional units but stay constant over time, and (2) the effects that are specific to time periods but are the same for every cross-sectional unit. For the remaining unobserved factors that vary in cross-sections and times, their effects are assumed to be individually unimportant, hence, can be treated as a random error that is uncorrelated with the observed variables.

Assuming that the unobserved year-specific effects are negligible, the state-fixed effect model can be represented by

$$Y_{it} = \mu + \sum_{i=1}^{N-1} \alpha_i + \sum_{k=1}^{K} \beta_k X_{itk} + U_{it} \qquad (4.2)$$

where μ is a fixed constant of the overall mean intercept

α_i is a set of the fixed constants of state-dummy variables

U_{it} is the random error term

Estimation of β in this model can be approached by least-squares dummy-variable (LSDV) estimator.

The above model is equivalent to the analysis-of-covariance model. β is equivalent to a covariance (CV) estimator, which can be estimated by

$$\hat{\beta}_{CV} = \left[\sum_{i=1}^{N}\sum_{t=1}^{T}(X_{it} - \bar{X}_i)(X_{it} - \bar{X}_i)'\right]^{-1}\left[\sum_{i=1}^{N}\sum_{t=1}^{T}(X_{it} - \bar{X}_i)(Y_{it} - \bar{Y}_i)\right] \quad (4.3)$$

According to the above formulation, all observed variables are transformed into the deviations from the mean values. Equation (4.2) can be rewritten by using the transformed variables as

$$Y_{it} - \bar{Y}_i = \sum_{k=1}^{K}\beta_k(X_{itk} - \bar{X}_i) + (U_{it} - \bar{U}_i) \quad (4.4)$$

Then, OLS estimates of the transformed variables can be used. It is noted that variables that do not vary over time in the same state are dropped from this model. *F*-statistics can be used to indicate statistical significance for the unobserved state-specific variations.

Random effect estimate

The second approach is to use a random-effect model that treats the unobserved state-specific effects as a random error. Assuming the time-specific random error to be negligible for every year, the random-effect model can be represented by

$$Y_{it} = \mu + \sum_{k=1}^{K}\beta_k X_{itk} + \alpha_i + v_{it} \quad (4.5)$$

where α_i is a random error specific to state i

v_{it} is the pure random error associated with both state and year

β is the generalized least-squares (GLS) estimator

Equation (4.5) can be revised to reflect the weighted average of within-effect and between-effect estimators as

$$Y_{it} - \theta \bar{Y}_i = (1-\theta)\mu + \sum_{k=1}^{K} \beta_k (X_{itk} - \theta \bar{X}_i) + (1-\theta)\alpha_i + (U_{it} - \theta \bar{U}_i) \qquad (4.6)$$

In a balance panel data set (i.e., each state panel has the equal number of temporal observations), θ is a constant term that represents a function of variances associated with the pure random error (U_{it}) and the state-specific error (α_i). The estimated θ can be derived from an error component model by using mean square errors from the within-effect and between-effect estimates (Baltagi, 1995). Breusch and Pagan Lagrangian multiplier test (1980) can be used to test for the significance of the random effects specific to state.

Comparison between fixed effect and random effect models

One distinction that can be made from the above estimation models is that in the fixed effect model the unobserved variations specific to cross-sectional units are represented by unknown parameters to be estimated. In the random effect model, these variations are treated as the normally distributed random error (Kmenta, 1986).

For statistical consideration, this gives an advantage to the random effect model over the fixed effect model. Because degrees of freedom can be saved, thus parameter estimates are more efficient. In the fixed effect model, effects of every state dummy variable need to be estimated, whereas these unknown parameters can be represented in the random effect model by variance of the state-specific error term.

There are two additional issues to be considered. The first one is whether the

estimated effects of the variables of interest (X) are conditional on the drawn sample or unconditional on the population characteristics. The fixed effect model views as the effects as conditional on the sample. When unconditional inference is made and the data are considered to be a random sample, the effects should be considered random (Hsiao, 1986).

If the unconditional inference is desired, there is another concern about the correlation between the unobserved cross-sectional (or time)-specific factor and the observed variables in the model. For example, if unobserved medical practice that tend to vary across states are correlated with both the policies of interest and Medicaid drug expenditures, estimation of the effects of these policy variables in the random effect model would be biased. The inclusion of a set of state dummy variables in the fixed effect model can resolve this omitted variable bias.

A useful argument made by Mundlak (1978) is that a model that allows for the correlation between unobserved cross-sectional effects and the observed variables will give the same estimate as when the cross-sectional effects are treated as fixed. Thus, the issue of whether α_i is random or fixed becomes unnecessary for the estimation technique. The more important issue is whether the unconditional distribution of α_i is equal to the conditional distribution of α_i given X_i. If the random effect model will be chosen, there is a need to test for the mis-specification of $Y_{it} = \mu + \sum_{k=1}^{K} \beta_k X_{itk} + \alpha_i + v_{it}$ where α_i is assumed random.

One way to test the randomness assumption for α_i is to test the null hypothesis of

no correlation between the unobserved random effect (α_i) and the observed explanatory variables (X_i), that is $E(\alpha_i X_{it}) = 0$.

Hausman (1978) suggested that under this null hypothesis, the GLS estimator for β from the random effect model achieves the Cramer-Rao lower bounds; but under the alternative hypothesis, the GLS is a biased estimator. The null hypothesis of no correlation under the Hausman's specification error test implies that both GLS and CV estimators are consistent. Because the CV estimator is not efficient, the random effect model is preferred under the null hypothesis.

The null hypothesis will be tested for the difference (q) between the CV estimates of β under the fixed effect model and the GLS estimates of β under the random effect model.

$$\hat{q} = \hat{\beta}_{CV} - \hat{\beta}_{GLS} \tag{4.7}$$

$$Var(\hat{q}) = Var(\hat{\beta}_{CV} - \hat{\beta}_{GLS}) \tag{4.8}$$

Under the null hypothesis, the covariance of an efficient estimator with its difference from an inefficient estimator is zero.

For K explanatory variables, the test statistic is $\hat{q}^{*}\left[Var(\hat{q})\right]^{-1}\hat{q}$ with χ^2 distribution with K degrees of freedom.

If the null hypothesis is rejected, the GLS estimator from random effect model is not consistent. Because the CV estimator is consistent under both the null and alternative hypotheses, the fixed effect model is more appropriate than the random effect model.

4.1.3 Simultaneous equation system

As stated earlier, all published studies to date considered drug benefit management policies as exogenous variables with respect to expenditures. If the state's decision to impose a restrictive benefit management policy is influenced by the unusually high Medicaid expenditures, ignoring endogeneity of the policy variable will result in a biased estimation of the policy effect on the expenditures. A simultaneous-equation model can be used to deal with this endogeneity problem by separating the effect of Medicaid expenditures on the decision to impose a restrictive policy from the effect of the policy on the expenditures.

The simultaneous-equation system can be formalized by

$Y_{it} = \beta_1 X_{it} + \beta_2 Z_{it} + u_{it}$ as the expenditure equation

$X_{it} = \gamma_1 Y_{i,t-1} + \gamma_2 W_{it} + v_{it}$ as the state policy decision equation

where Y_{it} is the endogenous expenditure variable observed in state i at year t

X_{it} is the endogenous policy variable observed in state i at year t

Z_{it} and W_{it} are the exogenous explanatory variables

u_{it} and v_{it} are the random error terms

The above equations suggest possibility of omitted variable bias for an estimation of the policy effect (β_1) in the expenditure equation. If the restrictive policies came into existence because the motivation to contain Medicaid expenditures in high cost states, the estimates of policy effects are biased toward the null or too positive.

This study uses a two-stage least squares method as an alternative approach to

estimate the effects of the three restrictive benefit management policies (Baltagi, 1995). In this case, a set of the instrumental variables for the endogenous state policies has to be specified. Variables that are used as the instruments are described along within the theoretical background for the endogenous Medicaid policy in last sub-sections of Section 2.

Maddala (1992) suggested the Hausman test for omitted variables (1978) to be used in the tests for exogeneity of the variables to be specified as exogenous in the simultaneous equations. First, the predicted values of the three policy variables are obtained from the reduced form equations for the endogenous state policies. The predicted policy variables are then included in the expenditure equation along with the original policy variables of interest and other covariates. Statistical significance of the coefficients for the predicted policy variables, considered together in this expanded regression equation would signal the endogeneity problem of the state restrictive policies.

All estimations of the parameters in this study are performed by Stata Statistical Software Release 6.0 (Stata Corp, College Station, TX).

4.2 Measurement

This study gathers the information from a number of separate data sources on Medicaid drug utilization and expenditures and state Medicaid program characteristics. Operational definitions and data sources for the variables to be specified in estimation models are summarized in Table 4.1.

Table 4.1

Variables in Medicaid drug utilization/expenditure equations

Variable	Description	Data source
Drug expenditures	CPI-adjusted Medicaid fee-for-service annual payments for prescribed drugs	HCFA-64 (UI-edited)
Drug recipients	Medicaid enrollees who received Medicaid drugs within a year under fee-for-service claim system	HCFA-2082
Prescription copayment policy	CPI-adjusted dollar amounts of copayment per prescription	NPC report
Prescription cap policy	Presence of monthly prescription limits	NPC report
Drug formulary policy	Percent of Medicaid drug products not reimbursed	HCFA public use files
Generic dispensing rate	Percent of prescriptions for multiple-source drugs filled by generic version	HCFA public use files
Single-source drug prescribing rate	Percent of prescriptions filled by single source drugs	HCFA public use files
Allowable drug ingredient cost	Percentage of AWP as the payment basis for non-MAC drugs and drugs prescribed with brand medically necessary	NPC report
Dispensing fee	CPI-adjusted dollar amounts of dispensing fee per prescription	NPC report
Total Medicaid population	Number of total Medicaid enrollees	HCFA-2082
Medicaid managed care penetration	Percent of total Medicaid population enrolled in managed care	Medicaid Managed Care Report
Socio-demographic mix of Medicaid population	% male and female Medicaid enrollees % Medicaid enrollees who are children in AFDC, adults in AFDC, low-income aged, low-income blind and disabled	HCFA-2082 HCFA-2082
Drug provision to medically needy	Presence of drug benefit provision for Medicaid enrollees with medically needy status	Medicaid Services State by State

4.2.1 Data Sources

State-year specific variables to be used in this study come from three major data sources. Medicaid drug expenditures, number of drug recipients, and Medicaid population characteristics are retrieved from Medicaid program statistics and financial reports that are based on data submitted by state Medicaid agencies to Health Care Financing Administration (HCFA). A proxy variable for restrictive drug formulary policy and variables representing mix of the reimbursed Medicaid drugs are developed exclusively from HCFA public use files of state-generated drug utilization data under the Medicaid drug rebate program. All other drug benefit management policy variables were abstracted from survey data published in the National Pharmaceutical Council (NPC) reports.

HCFA-2082 report

The Statistical Report on Medical Care: Eligibles, Recipients, Payments, and Services (HCFA-2082 form) is an annual statistical report that contains the unduplicated counts in each federal fiscal year (ending September 30) of Medicaid enrollees, recipients and payments by type of Medicaid service and by basis of Medicaid eligibility. Some states submit this report directly to HCFA. Other states submit person-level enrollment and claims data to HCFA for the Medicaid Statistical Information System (MSIS), then HCFA uses the MSIS data to generate the HCFA-2082 report.

In this study, numbers of all-eligible drug recipients and Medicaid enrollees as well as socio-demographic mix of Medicaid population for each state-year were extracted directly from the HCFA-2082 report.

HCFA-64 report

The Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (HCFA-64 form) is a report for the Medicaid program that individual states submit to HCFA on a quarterly basis. The report contains an accounting information on actual payments made by states for which they are entitled to receive the federal reimbursement under Title XIX (i.e., federal medical assistance percentage, FMAP) for that quarter. Data from the quarterly HCFA-64 are then combined to generate a summary report for each federal fiscal year. Information from HCFA-64, however, is limited to Medicaid expenditures by type of service and does not provide detail by basis of Medicaid eligibility as reported in HCFA-2082.

The payment amounts reported in HCFA-64 are considered to be more reflective of true Medicaid spending than the data from HCFA-2082 (Ku et al., 1990). The expenditure data from HCFA-64 have been reviewed and edited extensively by the Urban Institute (UI) to generate the national and state profiles and trends of all-recipient Medicaid expenditures for the report used in the Future of Medicaid project (Liska et al., 1997). These UI-edited data sets have been used in an earlier study on Medicaid policies and were claimed to be internally consistent and readily usable for the analysis across Medicaid eligibility status (Adams, 1995). Therefore, Medicaid drug expenditures in each state-year for this study were derived from the data in HCFA-64 that were edited by the Urban Institute.

HCFA public use files for Medicaid drug rebate program

Since the beginning of Medicaid drug rebate program in 1991, HCFA has made

available public use files of the utilization data of Medicaid drugs that were under rebate agreements. These state-generated data contain quarterly information by drug products on payments and number of prescriptions and drug dosage units of drugs that have been reimbursed in every state except Arizona and Tennessee (after the federal fiscal year 1993). Average number of the Medicaid drug products reported during the study period (from the fourth quarter of 1991 to the third quarter of 1996) ranged from 5,927 (in Alaska) to 23,406 (in New York) line items. These drug products are uniquely identified by National Drug Code (NDC)[1].

Even though these public use files contain observations on expenditures and utilization of Medicaid drugs at the most-detailed level by NDC, the available information is incomplete. The observation unit cannot be aggregated into a meaningful unit of analysis without data editing and imputation for missing values.

About 11-16% of total observations in each quarterly data did not contain the manufacturer or labeler code of the NDC. Some observations (about 1-5%) of the quarterly data before 1993 did not have information on drug names. Several observations contained either inconsistent drug names across states or typo error. The incomplete NDC and the missing drug names have been recovered and the inconsistent or error drug names have been corrected by using an information from Medispan's Master Drug Database (MDDB), a commercial database owned by First Databank.

The second problem concerns missing data in certain quarters. Of the 49

[1] The 11-digit NDC consists of 5-digit manufacturer or labeler code, 4-digit active ingredient-dose form-strength code, and 2-digit package code.

Medicaid jurisdictions, 30 states (61.2%) reported the drug utilization data for all 20 quarters of the five-year study period. However, twelve of these 30 states had reports that contain abnormally small number of observations (less than 2 standard deviations of the mean) up to 3 quarters. Nine states (18.4%) did not report in 1 quarter and one of them had 1 quarter of the thin reported data. Six states (12.2%) had no reports for 2 quarters and one of them also had the thin data in 1 quarter. The other 4 states did not report in 3 – 6 quarters and three of them also had 1 quarter of the thin data each.

An imputation for the missing quarters and missing observations is done at a new level of observations instead of the NDC level. This is a result of linking the edited Medicaid files to the MDDB by NDC. Information from MDDB with regard to drug accessibility status (prescription vs. over-the-counter), therapeutic characteristics (identified by Generic Product Identification or GPI[2]), and market status (single source vs. innovative and non-innovative multi-sources) when augmented to the original Medicaid drug data can be used as the reference level for data imputation.

NDC-level drug products that have the same prescription status, equivalent GPI, and same market status are aggregated in a new unit of analysis for data imputation. For a given state with incomplete data, data for the missing quarters are imputed to be equal to quarterly average from the available quarters of the equivalent drug product in the same calendar year. These imputed quarterly data are ready for the next step of data aggregation as in the states with complete quarterly data.

[2] The 14-digit GPI consists of 6-digit code of drug class and subclass, 4-digit code of active ingredient or chemical entity, 2-digit code of dose form, and 2-digit code of strength

Expenditures and number of prescriptions of each drug product from the fourth quarter of a previous calendar year are combined with those from the first three-quarters of a current year to yield the annual amounts for the current federal fiscal year (ending September 30). The yearly data of drug products that have the same prescription status and equivalent drug class and active ingredient (the first 10 digits of GPI) and route of administration are collapsed and categorized by market status. This refined level of observation forms the final unit of analysis that can capture variations in drug formulary restriction and mix of the Medicaid reimbursed drugs.

NPC reports

The reports entitled 'Pharmaceutical Benefits under State Medical Assistance Programs' published by the National Pharmaceutical Council (NPC) contain the annual survey data on state drug benefit management policies. Data from these reports have been used by several past studies of Medicaid drug cost containment. In the publications, there are certain discrepancies between the data reported in the fifty-state summary tables and the detailed descriptions of the individual states. This study derives information on four policy variables including prescription copayment, prescription cap, allowable drug ingredient cost and dispensing fee from the individual-state descriptions of Medicaid drug benefits rather than the summary tables.

This study defined the beginning of yearly period according to the beginning of the federal fiscal year, which is in October of the preceding calendar year. The policy changes that have been known for the effective dates after April in a given calendar year were assumed to be in effect in the following yearly period. Most states reported the

policy changes in July or August. Hence, the change is counted in the following yearly period.

4.2.2 Measured variables and definitions

Drug expenditures

Drug expenditures are derived from annual Medicaid payments for the prescribed drugs that were dispensed by retail pharmacies under the fee-for-service claim system. The payments are presented as gross amounts paid by state Medicaid agencies prior to the receipt of rebate amounts from drug manufacturers. Current-year dollars are adjusted by all-item Consumer Price Index urban (CPI-u) to account for the economy-wide inflation over time.

Dependent variable in the first equation of expenditures is represented by total drug expenditures in a given state-year divided by total number of Medicaid enrollees in the same state-year. This per enrollee adjustment allows controlling for differences in the sizes of Medicaid population (as the potential users of prescribed drugs) among states and changes in Medicaid population size within a state over time.

To capture state variations on drug expenditures specific to Medicaid drug recipients in a given year, the dependent variable in the second equation of expenditures is indicated as total drug expenditures divided by number of drug recipients of the same state in that year. The per recipient expenditures can be used to reflect the intensity of drug expenditures in only Medicaid population with non-zero use, which is the second part of the over all expenditures per enrollee.

Drug recipients

The proportion of total Medicaid enrollees who are drug recipients reflects magnitude of the first part of the utilization related to drug expenditures in a given state-year. Assuming a similar probability of any drug use among comparable Medicaid enrollees, the dependent variable in the third estimation equation related to Medicaid drug expenditures is the proportion of Medicaid enrollees who had one or more prescriptions reimbursed from Medicaid programs in a given year. This derived variable captures variations in propensity of use (fraction of the non-zero use) at the state level.

Prescription copayment policy

Variation in patient cost-sharing policy with regard to Medicaid prescriptions is captured by the dollar amount required by each state Medicaid agency for drug recipient contribution to a reimbursed prescription in a given year. In the 14 states that had varying amounts of copayment, the maximum dollar amount is chosen. Current-year dollars are deflated using the all-item CPI-u adjustment.

Prescription cap policy

Prescription cap policy is measured by a binary variable representing the presence or absence of monthly prescription limit in each state-year. Because this policy variable is expected to affect only Medicaid enrollees who had multiple drug use, it is not specified in the propensity of use equation.

Drug formulary policy

One way to define the degree of the restriction with respect to Medicaid drug formulary policy is to quantify variations in the availability of Medicaid drugs that are

potential substitutes across states and over time. This study considered number of the drug products with common therapeutic indications that were not reimbursed in a state as a proxy for the restrictive drug formulary in that state. Unlike a simple binary classification of state drug formulary as presence vs. absence that has been used in most prior studies, this fine-tuned variable seems to conform with the main purpose of drug formulary that would allow for therapeutic substitution of the drug products deemed inappropriate for Medicaid reimbursement.

There are two major steps in the development of this proxy variable from the MDDB-matched Medicaid public use files in this study. First, Medicaid drug non-reimbursement rate for every drug class is calculated. Drug products that have the same therapeutic class as indicated by the first 6 modified digits of GPI are deemed potential substitutes and are grouped together. The maximum availability of Medicaid drugs for that class in a given year is measured by the total counts of drug products (uniquely identified by chemical entity, route of administration, and prescription status) that have been reimbursed in any of the 49 states. For each state-year, the drug non-reimbursement rate in a given drug class is calculated as the percentage of the defined drug products that were not reimbursed.

Second, this study selects a data subset consisting of the most common therapeutic indications of Medicaid drugs. Specifically, the top fifty drug classes ranked by number of reimbursed prescriptions in any states and in any of the five years are chosen to form a common panel for generating the state-year specific variable. Inclusion of the most widely used drug classes controls for under-representation of the small states.

Medicaid reimbursement for the uncommon therapeutic indications probably does not show up in a state that has a small number of Medicaid enrollees. Weighted average of the non-reimbursement rate in the defined top 50 drug classes for each state-year yields the non-reimbursement rate variable to be used in this study.

Generic dispensing rate and single source drug prescribing rate

Mix of Medicaid prescriptions with regard to market status of the reimbursed drug products is captured by two variables developed specifically for this study. One is the generic dispensing rate and the other is the single-source drug prescribing rate. Generic dispensing rate is defined as proportion of prescriptions for the off-patent, multi-source drugs that were dispensed or filled by generic drug products. Single source drug prescribing rate is defined as the proportion of all-source prescriptions that were prescribed and dispensed or filled by the patent-protected, single source drugs.

As stated earlier, these two variables are specified in the per recipient and per enrollee expenditure equations for two purposes. First, Medicaid payment per prescription depends primarily on the type of drug product that is reimbursed. The payment basis for the drug ingredient cost of several multi-source drug products is determined by the listed maximum allowable cost (MAC), which is capped at the generic price. Second, these two variables are expected to capture state variations in medical practice as a result of a variety of generic substitution policies implemented in several states.

This study derives the state-specific generic dispensing rate and single source drug prescribing rate from the MDDB-matched Medicaid public use files. Drug products

with the same prescription status and the equivalent active ingredient (first 10 digits of GPI) plus route of administration are combined together to form the grouping variable. The denominators in these two variables are based on total counts of the reimbursed prescriptions at the level of this grouping variable. For the numerator, product differentiation based on market status as single source, innovative multi-source, and non-innovative multi-source (or generic) drugs is based on observations of drugs with the same prescription status and all 14 digits of GPI (equivalent active ingredient, dosage form, and strength). For a given Medicaid drug product, the generic dispensing rate is the ratio of prescriptions filled by generic products to total prescriptions for multi-source drugs. The single source drug prescribing rate is equal to the ratio of single source prescriptions to all-source prescriptions for the same drugs.

Whereas the drug non-reimbursement rate is based on a data set derived from the top 50 most-used drug classes, market mix of the reimbursed prescriptions is derived from the top 200 drug products ranked by Medicaid expenditures in any state-years. Weighted averages of the generic dispensing and single source drug prescribing rates across all drug products in this subset of data yields the state-year specific variables.

Allowable drug ingredient cost

Drug products that Medicaid payment basis is not subject to the prevailing generic prices include single source drugs, multi-source drugs not in the MAC lists and multi-source drugs prescribed with brand medically necessary. For prescriptions of these non-MAC drugs, Medicaid payment basis is set to the lowest of (1) the estimated acquisition cost (EAC) plus dispensing fee or (2) the usual and customary charges.

Most states define EAC as a fraction (up to 100%) of the average wholesale price (AWP) of drug products. Certain states specify EAC proportional to the wholesale acquisition cost (WAC). For the latter states, the ratios between WAC and AWP averaged across all single source drugs are used for the transformation of WAC into AWP. Available data from Medispan's MDDB database suggest the mean ratio of 1.25 to be used for this conversion purpose.

Dispensing fee

Dollar amounts of dispensing fee per prescription that were allowed by each state are used to control for variation in the Medicaid payment basis over and above the allowable drug ingredient cost. For the 18 states that have a varying schedule for dispensing fees, the lowest amount is used in this study. Current-year dollars will be converted to constant dollars by the all-item CPI-u.

Total Medicaid enrollees

The total number of Medicaid enrollees in the state is used in an adjustment for the difference in size of the states for two purposes. As a denominator in the dependent variable, the all-eligibility Medicaid population controls for differences in the total number of potential users of Medicaid drugs. As a model covariate, number of Medicaid enrollees in a state reflects magnitude of the overall need of prescriptions. This variable controls for the tendency that a small state will have a high non-reimbursement rate due to a relatively low need.

In the general population, previous studies have found state variations in personal healthcare spending associated with differences in the proportion of population that is

elderly across state regions (Levit, 1985; Levit et al., 1993). About 12% of the general population were the elderly who accounted for over 34% of prescription drug expenditures (Thomas and Schondelmeyer, 1990). For the Medicaid population, the difference in underlying medical need intensity across states is captured by two sets of variables: gender mix and mix of eligibility status of the enrollees in each state.

Gender mix of Medicaid population

Variable representing gender mix of Medicaid population is computed directly from percentage of Medicaid enrollees who were male or female. To avoid multi-collinearity problem, only the female proportion of Medicaid enrollees (*ENRFM*) is used.

Mix of Medicaid eligibility

Medicaid population by basis of Medicaid categorical eligibility regardless of cash-assistance status was combined into four major groups: children in the Aid to Family with Dependent Children (AFDC) program, adults in AFDC families (*ENRAD*), low-income elderly (*ENRAG*), and low-income blind and disabled (*ENRBD*). A small number of Medicaid enrollees who were not reported in these four groups were excluded. Medicaid enrollees in each eligibility group as a percentage of all-four-group enrollees: *ENRAD*, *ENRAG*, and *ENRBD* are used as covariates.

Provision of drug benefits to medically needy

Certain states also extend the prescription drug benefits to the Medicaid enrollees who are eligible under medically needy status. A dummy variable (*ENRMN*) representing the presence of this optional benefit provision will be specified.

Medicaid managed care penetration

A variable representing managed care penetration rate in state Medicaid programs is derived from the ratio of the number of Medicaid beneficiaries enrolled in managed care organization to the total number of Medicaid beneficiaries.

This variable is used for two purposes. First, to adjust for the difference in number of potential drug users in fee-for-service segment because the study dependent variable reflects only the fee-for-service payments and recipients as a fraction of total Medicaid enrollees. Because the data source for total Medicaid population (HCFA-2082 annual report) is different from Medicaid managed care enrollee data (Medicaid managed care mid-year survey), this variable is used as a control variable rather than as a direct adjustment of the dependent variable. Second, Medicaid managed care in the states with relatively high penetration rates might have a spillover effect on the fee-for-service expenditures.

4.3 Instrument variables for endogenous state Medicaid policies

Drug benefit management policy is an easy option that the state governments can exercise to reduce excessive and expensive service utilization created by the open-ended Medicaid program. This study accounts for pre-existing expenditure levels, which may have led states to adopt restrictive drug benefit management policies.

4.3.1 Theoretical basis for the endogenous Medicaid policy

Most prior empirical studies on Medicaid and other welfare-related public policies

have used the Median Voter/Taxpayer Model for their theoretical basis (Orr, 1976; Grannemann, 1979; Cromwell et al., 1984; Sloan, 1984). Voter/taxpayer's willingness to pay for the Medicaid program *versus* other government expenditures is subject to income constraint, represented by tax capacity and set equal to a linear function of tax price that the voter has to pay for the provision of Medicaid program.

A study by Wade and Berg (1995) used the pooled time-series data of state policy determinants to explain Medicaid expenditure growth. The study included the following key variables based on the Median Voter/Taxpayer Model: (1) Tax price as a function of federal Medicaid matching rate, tax exportation rate, medical price index, and population over 18 years of age representing taxpayers/voting population; (2) Tax capacity using median household income as a proxy; and (3) political ideology of the administrator using party affiliation of state governor as a proxy. Another study investigating generosity of Medicaid policies toward service recipients and providers has used the same theoretical model (Reutzel, 1989). The study included similar key variables representing tax price and tax capacity: the federal matching rate, medical price index, and per capita income. In addition, a set of regional locations of states based on the census regions were used as a proxy of political preference on Medicaid administration.

The other approach uses models developed from the Political Choice Theory known as the Peltzman Model (Peltzman, 1976). Two studies on endogenous hospital rate setting policy mandated in certain states have used certain political variables to represent political culture and economic variables to represent costs of enacting such a policy (Cone and Dranove, 1986; Lanning et al., 1991). Another study of Medicaid

eligibility criteria and benefit generosity also used both political and economic variables adapted from the above model (Grogan, 1991). These included the federal matching rate and per capita income for the economic factors; party control over state administration and legislature, health interest group strength, and an index of political culture for political factors; and a set of socio-demographic variables representing underlying demands for Medicaid program.

4.3.2 Political choice model

This study formalizes a model for the endogenous drug benefit management policies by a modification of a model of political choice proposed by Cone and Dranove (1986) to explain a state's enactment of hospital rate-setting laws. According to that model, states will provide a politically optimal level of Medicaid benefits by maximizing their political utility. States would like to satisfy the utility of voters/taxpayers and their own political ideology. At the same time, they seek to minimize the political dis-utility by attempting to keep the political cost of transfers from tax payers to Medicaid recipients as low as possible. An increase in the Medicaid expenditures would increase the political dis-utility because the state would require more revenue through increased taxation to fund the additional Medicaid benefits.

A study by Soumerai et al. (1997) using in-depth interviews with key informants in 19 state Medicaid agencies revealed that budgetary and economic conditions are the primary factors for the tightened prescription cap or copayment policies during 1986-1993. The present study includes both economic and political factors that have been used

by past studies of Medicaid policies for model specification of the endogenous drug benefit management policies.

Variables to be used as the instruments of state Medicaid policy variables are summarized in Table 4.2

Table 4.2

Instrumental variables for the endogenous state Medicaid policies

Variable	Description	Data source
State political culture	Dominant perception of population toward politics: classified as traditionalistic, individualistic, or moralistic states	Elazar (1988)'s American Federalism: A View from the States
Political party control	Party affiliation of state governor	Book of the States
State income	CPI-adjusted state per capita income	Statistical Abstract of the US
Medicaid expenditure burden	Medicaid total medical vendor payments as a proportion of state expenditures	HCFA-64 Book of the States
Federal matching rate	Federal medical assistance percentage (FMAP) allocated to states	
State population	Total state population	Statistical Abstract of the US
Managed care penetration	Percentage of total population enrolled in health maintenance organizations	Inter Study

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CHAPTER 5

RESULTS

This chapter is divided into 4 major sections. The first section presents descriptive statistics on Medicaid drug expenditures and related variables showing their variation across states and over time. Next, this section presents information on three variables that were developed specifically for this study using drug product-level observations. The three variables are: (1) proportion of drug products with the same indication that were not reimbursed as a proxy for the restrictiveness of the drug formulary; (2) generic dispensing rate; and (3) single source prescribing rate.

The second major section focuses on empirical findings from an estimation of the expenditure equation that uses drug expenditures per Medicaid enrollee as the dependent variable. The impact of the three drug benefit management policies was evaluated using two statistical approaches: (1) a cross-sectional ordinary least squares (OLS) regression and (2) a pooled cross-sectional time-series regression. The final two sections present the findings from two additional estimation models that were based on the components contributing to drug expenditure per enrollee per year. Section three results are related to the drug expenditure per drug recipient per year and section four results are related to the proportion of all Medicaid enrollees who are drug recipients.

Table 5.1A

Medicaid drug expenditures and recipients, 1992-1996

	Federal fiscal year				
	1992	1993	1994	1995	1996
Drug expenditures (*DRUGEXP*)					
per enrollee N (all states)	49	49	49	49	49
- Current-year dollars					
Minimum	135.97	139.18	134.98	137.20	118.25
Maximum	362.58	354.80	373.46	407.76	458.77
Unweighted mean	210.90	229.06	249.28	271.67	299.98
Standard deviation	44.65	50.10	55.26	65.00	77.31
Enrollee-weighted mean	201.88	217.62	237.01	259.56	285.49
- 1996-constant dollars mean	235.85	248.71	263.91	279.69	299.98
per recipient N (exclude HI and RI)	47	47	47	47	47
- Current-year dollars					
Minimum	220.37	239.85	269.48	273.59	295.95
Maximum	486.21	486.83	539.41	611.38	748.15
Unweighted mean	335.13	358.39	393.14	448.56	513.09
Standard deviation	56.03	58.67	63.60	79.06	98.03
Recipient-weighted mean	323.57	349.31	384.63	433.10	495.42
- 1996-constant dollars mean	374.78	389.14	416.22	461.81	513.09
Drug recipients (*DRUGREC*)					
per 100 enrollees N (exclude HI and RI)	47	47	47	47	47
Minimum	45.6	46.7	42.5	37.0	32.7
Maximum	74.6	74.6	75.6	74.9	75.7
Unweighted mean	62.6	63.3	62.9	61.2	59.4
Standard deviation	7.2	7.0	8.2	9.7	10.5
Enrollee-weighted mean	62.3	62.2	61.6	60.1	57.8

5.1 Descriptive statistics

5.1.1 Dependent variables

Table 5.1A presents summary statistics of the three dependent variables to be used in the estimation models: (1) Medicaid drug expenditures per Medicaid enrollee; (2) Medicaid drug expenditures per drug recipient; and (3) Medicaid drug recipients as a proportion per 100 Medicaid enrollees.

Drug expenditures

Medicaid drug payments in current-year dollars per Medicaid enrollee reveal a steadily increasing trend over time. Averaged across the 49 Medicaid jurisdictions, the annual per enrollee drug expenditure increased from $210.90 in 1992 to $299.98 in 1996. The annual growth rate was 9.2% over the study period. The rate of growth in the overall economy (all-item CPI-u) over this same time period averaged 2.8%. Even after adjusting for inflation (using 1996-constant dollars), the per enrollee drug expenditures rose at an average annual rate of 6.2% per year.

Time trends of national Medicaid drug expenditures can be illustrated by changes in state-average expenditures that are weighted accordingly to the number of total Medicaid enrollees in each state. The resulting enrollee-weighted average expenditures continue to show the increasing trend with a similar average growth rate of 9.1% per year. An increasing trend of these weighted average expenditures is consistent with the findings from a study by Baugh DK, et al. (1999) observing changes in the national Medicaid drug expenditures during 1990–1997 but with a different degree of growth.

Medicaid drug payments in each year also vary across the 48 states and the

District of Columbia. The standard deviation of per enrollee expenditures for each year increases from $44.65 in 1992 to $77.31 in 1996. Variation in expenditures across states seems to be independent of size of the states controlling for the size of the Medicaid population. Over the five-year period, the highest expenses (mean $\pm$ SD) are found in Indiana ($373.17 $\pm$ 32.65), New Jersey ($368.81 $\pm$ 61.30), Maine ($343.82 $\pm$ 76.55), Louisiana ($336.38 $\pm$ 43.32), and Nebraska ($335.90 $\pm$ 51.38). On the other end, five states with the lowest expenditures are Nevada ($146.42 $\pm$ 10.55), New Mexico ($151.78 $\pm$ 14.03), California ($179.28 $\pm$ 20.87), Oregon ($180.51 $\pm$ 22.62), and Hawaii ($186.82 $\pm$ 56.20).

Drug expenditures for the Medicaid population who received prescribed drugs show a similar time trend with a relatively higher magnitude of the average growth rate of 11.3% per year. The per recipient expenditures in current-year dollars averaged across 47 Medicaid jurisdictions (excluding Hawaii and Rhode Island) increase from $335.13 in 1992 to $513.09 in 1996. Controlling for the inflation rate, the average annual per recipient expenditures in 1996-constant dollars increase to a lesser degree (8.2%).

The top 5 states with highest expenditures per recipient (mean $\pm$ SD) include New Jersey ($546.59 $\pm$ 131.09), Wisconsin ($544.01 $\pm$ 84.03), Indiana ($529.60 $\pm$ 72.60), Maine ($514.36 $\pm$ 108.49), and Pennsylvania ($505.75 $\pm$ 111.18). Five states with the lowest per recipient expenditures are New Mexico ($264.12 $\pm$ 23.69), Texas ($269.39 $\pm$ 41.88), Georgia ($319.91 $\pm$ 32.84), Wyoming ($320.79 $\pm$ 57.98), and California ($326.99 $\pm$ 41.83).

Drug recipients

The proportion of Medicaid enrollees who had their prescribed drugs reimbursed from Medicaid at least once a year decreased from an average of 62.6% in 1992 to 59.4% in 1996, excluded Hawaii and Rhode Island. The propensity of Medicaid drug use (fraction of the non-zero use or the first part of the per enrollee expenditures) decreases slightly on an average of 1.3% per year. The enrollee-weighted average number of drug recipients per 100 enrollees decreases at 1.8% per year.

Averaged over the five-year period, the top five states with the highest fractions of Medicaid drug recipients are Louisiana (74.9%), Nebraska (74.0%), Mississippi (72.7%), Kentucky (72.1%), and Vermont (71.4%). The smallest fractions of drug recipients are found in Nevada (44.8%), District of Columbia (45.7%), Alaska (46.8%), Oregon (47.5%), and Maryland (50.5%).

State variations in Medicaid drug expenditures per enrollee can be driven by differences in the fraction of drug recipients, or the per recipient expenditures, or both. In this study, pair-wise correlation shows the statistical significance in the positive relationship between the per enrollee expenditures and the two components in every year. For the first part of the per enrollee expenditures, a measure of drug recipients proportional to total Medicaid enrollees shows the correlation coefficients of 0.64, 0.67, 0.70, 0.65, and 0.63 in 1992, 93, 94, 95, and 1996, respectively ($P < 0.01$). States with relatively high ranks in number of drug recipients per 100 enrollees like Louisiana and Nebraska also appear among the top five states ranked by expenditures per enrollee. Nevada and Oregon are among the relatively low rank group in both drug recipient

fraction and the per enrollee expenditures.

The correlation coefficients between the per enrollee expenditures and the per recipient expenditures during the same periods are 0.81, 0.86, 0.81, 0.69, and 0.68 respectively ($P < 0.01$). Even though the expenditures conditional on any use shows a relatively higher degree of positive relationship with the per enrollee expenditures, not every state ranks perfectly in the same order with respect to the two measures of state drug expenditures.

In sum, descriptive statistics reveal the opposite time trends between the two measures related to the first and the second components of the per enrollee expenditures. While the propensity of drug use measured by number of drug recipients per 100 enrollees decreases gradually, the intensity of expenditures per drug recipient increases over time. This implies that the growth of Medicaid drug expenditures per enrollee is driven mostly by an increase in the intensity of expenditures (a product of Medicaid payment rate and intensity of use) among the drug recipients. An increase in the propensity of any use or fraction of the drug recipients seems to play a minor role.

5.1.2 Medicaid population

Table 5.1B describes characteristics of Medicaid population over the five years of study period. This study considered all Medicaid enrollees as the population at risk for Medicaid drug utilization. Hence, each enrollee has a similar chance to incur Medicaid drug expenditures when adjusted for other covariates.

Table 5.1.B

Medicaid population characteristics, 1992-1996

	Federal fiscal year				
	1992	1993	1994	1995	1996
Total Medicaid enrollees (*ENRTOT*)					
Minimum	49,216	53,254	56,501	57,553	56,254
Maximum	6,060,056	6,478,545	6,778,151	6,774,415	6,620,514
Mean	700,364	758,013	794,205	807,435	799,422
Standard deviation	996,697	1,076,216	1,126,374	1,126,665	1,107,100
Male enrollees (*ENRML*) %					
Minimum	35.5	36.2	36.6	37.1	36.7
Maximum	41.3	41.4	42.4	43.6	44.0
Unweighted mean	38.3	38.8	39.2	39.4	39.7
Standard deviation	1.5	1.4	1.4	1.5	1.5
Enrollee-weighted mean	38.5	38.9	39.3	39.6	39.7
Female enrollees (*ENRFM*) %					
Minimum	58.7	58.6	57.6	56.4	56.0
Maximum	64.5	63.8	63.4	62.9	63.3
Unweighted mean	61.7	61.2	60.8	60.6	60.3
Standard deviation	1.5	1.4	1.4	1.5	1.5
Enrollee-weighted mean	61.5	61.1	60.7	60.4	60.3
AFDC-child enrollees (*ENRCH*) %					
Minimum	39.7	40.3	41.5	35.0	33.6
Maximum	58.9	60.0	60.2	62.3	63.4
Unweighted mean	52.0	52.2	52.2	52.3	52.1
Standard deviation	4.2	4.3	4.2	4.9	5.1
Enrollee-weighted mean	52.5	52.5	52.4	52.2	51.8

Table 5.1.B (continued)

	Federal fiscal year				
	1992	1993	1994	1995	1996
AFDC-adult enrollees (*ENRAD*) %					
Minimum	15.9	15.5	15.0	14.0	13.1
Maximum	32.1	30.4	36.1	46.8	47.5
Unweighted mean	23.0	22.6	22.2	21.8	21.2
Standard deviation	3.1	3.1	3.7	4.8	5.0
Enrollee-weighted mean	23.4	23.3	23.0	22.5	21.9
Aged enrollees (*ENRAG*) %					
Minimum	5.4	5.2	5.0	4.9	4.8
Maximum	18.9	19.1	19.1	16.4	16.6
Unweighted mean	11.2	10.8	10.7	10.3	10.4
Standard deviation	3.1	3.0	2.9	2.5	2.5
Enrollee-weighted mean	10.6	10.2	10.1	10.0	10.1
Blind/disabled enrollees (*ENRBD*) %					
Minimum	7.3	7.3	7.8	6.1	7.6
Maximum	21.2	22.6	24.7	25.1	26.5
Unweighted mean	13.8	14.4	15.0	15.5	16.3
Standard deviation	3.1	3.4	3.7	4.0	4.2
Enrollee-weighted mean	13.5	14.0	14.5	15.2	16.2
Provision of drug benefit for medically needy enrollees (*MEDNEED*) Yes (%)	69.4	69.4	69.4	69.4	69.4
Medicaid managed care penetration (*MCDMC*) %					
Minimum	0	0	0	0	0
Maximum	46.5	60.4	62.1	69.0	77.6
Mean	9.2	11.6	17.5	24.1	31.4
Standard deviation	12.6	14.8	18.4	19.7	21.1

Total Medicaid enrollees

There was wide variation in the size of total Medicaid population across states. The number of persons ever enrolled in Medicaid programs in a year during the study period (mean ± SD) ranged from 54,556 (± 3,386) enrollees in Wyoming to 6,542,336 (± 296,751) enrollees in California. To compare across states, state Medicaid enrollees (the potential users of prescribed drugs) were used as the denominator for both drug expenditure and drug recipient variables. Effects of this 'at risk' adjustment on the ranks of the states with regard to the expenditure ratio and the recipient proportion are ambiguous. A relatively large state like California has low drug expenditures per Medicaid enrollee over the five years. In parallel, a less populated state like Nebraska with 174,403 (± 7,303) Medicaid enrollees was among the top five states in both drug expenditures and drug recipients per Medicaid enrollee. However, Nevada with relatively small number of enrollees (126,171 ± 20,375) was ranked low in both expenditures and recipients per enrollee.

Gender mix of enrollees

Taking demographic characteristics into consideration, gender mix of the Medicaid population was quite stable over time. In a given year, the enrollee-weighted average figures in demographic mix are not different from the simple mean across states. Female enrollees averaged across states decreased slightly from 61.7% in 1992 to 60.3% in 1996. Across states, female enrollees represented 57.7% (in Vermont) to 63.3% (in North Carolina and New Jersey) of the state Medicaid population.

Medicaid eligibility mix

Regardless of cash assistance status, the majority of Medicaid enrollees were children in AFDC families. The five-year averages of this demographic category ranged from 42.8% in Rhode Island to 59.7% in New Mexico. The second largest category consisted of low-income adults in AFDC families, which comprised 14.7% (in Mississippi) to 28.8% (in California) of the state Medicaid population.

The proportion of the Medicaid population eligible because of blind and other disabilities, averaged across states, increased from 13.8% in 1992 to 16.3% in 1996. Over the same time period, the low-income elderly as a percentage of total Medicaid enrollees decreased slightly from 11.2% to 10.4% and the AFDC-adult category, from 23.0% to 21.2%.

Provision of Medicaid drug benefits to medically needy

In 1992, thirty-four states (69.4%) provided prescription drug benefits to Medicaid enrollees who were eligible under the "medically needy" status. The expansion of the Medicaid benefits to Medicaid population beyond the typical "categorical" enrollees in these 34 states continued through the end of the study time period.

Medicaid managed care enrollees

In recent years, several states encouraged a major portion of their Medicaid enrollees, especially those who were children and adults to be enrolled in managed care. The average proportions of Medicaid managed care enrollees increased markedly from 9.2% in 1992 to 31.4% in 1996.

An increasing standard deviation from 12.6 to 21.1% over the same period

indicated a difference across states in the rates of growth of the managed care penetration rates. There were almost no Medicaid managed care enrollees in Alaska, Maine, Vermont, and Wyoming in every year of the study period. States without Medicaid managed care in 1992 that shifted to managed care plans toward the end of study period included Arkansas (38.0% in 1996), North Dakota (38.3%), Montana (45.4%), South Dakota (47.5%), Connecticut (48.1%), Rhode Island (48.2%), and Delaware (60.2%). In 1996, states that had more than half of the Medicaid population enrolled in managed care were Washington (77.6%), Oregon (73.7%), Virginia (63.5%), Hawaii (61.0%), Delaware (60.2%), Michigan (59.2%), Colorado (57.5%), Massachusetts (57.1%), and Maryland (51.6%).

The effects of an increase in the Medicaid managed care penetration rate on drug expenditures and recipients are subtle. States with high percentage of managed care penetration would have less total 'at risk' population (i.e., potential users of prescribed drugs) left in the fee-for-service segment. This would result in relatively low drug expenditures or recipients per Medicaid enrollee in the fee-for-service system unless there was a biased selection of the relatively healthy people enrolled in managed care. Oregon and Hawaii (i.e., states with high managed care penetration and low drug expenditures per enrollee) seemed to fit under this category.

Table 5.1.C

Medicaid drug benefit management policy-related variables, 1992-1996

	Federal fiscal year				
	1992	1993	1994	1995	1996
Prescription copayment (*COPAY*)					
Copayment states (N)	24	27	29	29	31
Current-year dollars (in copay states)					
Minimum	0.50	0.50	0.50	0.50	0.50
Maximum	3.00	3.00	3.00	3.00	3.00
Mean	1.18	1.34	1.34	1.37	1.62
Standard deviation	0.54	0.72	0.72	0.73	0.80
Prescription cap policy (*PRESCAP*)					
Yes (%)	22.4	20.4	22.4	22.4	22.4
Non-reimbursement rate (*NRR*) %					
Minimum	15.5	16.8	13.9	15.1	16.2
Maximum	44.7	40.8	38.5	38.4	39.1
Mean	29.7	28.6	25.6	26.3	27.8
Standard deviation	6.8	6.4	6.3	6.3	6.1
Generic dispensing rate (*GDR*) %					
Minimum	21.6	30.9	39.5	40.6	42.0
Maximum	41.9	43.8	50.7	60.2	62.8
Mean	32.6	37.5	44.1	49.3	51.8
Standard deviation	3.7	2.7	2.5	3.3	3.8
Single-source drug prescribing rate (*SPR*) %					
Minimum	28.4	33.5	37.3	43.6	50.8
Maximum	41.4	46.4	51.6	57.4	61.0
Mean	33.7	39.0	44.2	50.1	55.9
Standard deviation	2.3	2.5	2.4	2.6	2.5

Table 5.1.C (continued)

	Federal fiscal year				
	1992	1993	1994	1995	1996
Allowable ingredient cost (*INGCOST*)					
As % of average wholesale price					
Minimum	85.6	85.6	85.6	85.6	84.0
Maximum	100.0	100.0	100.0	100.0	100.0
Mean	91.5	91.3	91.5	91.2	90.1
Standard deviation	3.7	3.5	3.5	3.4	2.6
Dispensing fee (*DISPFEE*)					
Current-year dollars per prescription					
Minimum	2.00	2.00	2.00	2.00	2.00
Maximum	5.60	5.60	5.60	5.77	5.77
Mean	4.05	4.06	4.06	4.12	4.07
Standard deviation	0.72	0.73	0.73	0.72	0.74

5.1.3 Restrictive drug benefit management policies

Table 5.1C presents descriptive statistics of variables related to Medicaid drug benefit management policies. The policy variables of primary interest are prescription copayment, prescription cap, and restrictive drug formulary. Drug non-reimbursement rate derived from individual drug-level observations is used as a proxy for the restrictiveness of the drug formulary policy. Two variables representing mix of the reimbursed Medicaid drug products are generic dispensing rate and single-source drug prescribing rate. Other two variables capturing variations in Medicaid payment rate are

allowable drug ingredient cost and dispensing fee per prescription.

Prescription copayment

In certain years during the study period, prescription copayment policies were implemented in majority of the states. Fourteen of the copay states had a varying schedule of the dollar amount required for the copayment. Medicaid drug recipients were required to pay a maximum of $0.50 to $3.00 per prescription. The number of the copay states has increased gradually from 24 states in 1992 to 31 states in 1996 with an increase in the average maximum amounts of copayment from $1.18 to $1.62 over the same time period.

Of the 49 Medicaid jurisdictions, 31 states (63.3%) reported either having or not having the copayment policies for every year. The fifteen non-copay states consisted of Connecticut, Delaware, Hawaii, Idaho, Illinois, Kentucky, Minnesota, North Dakota, New Jersey, New Mexico, Nevada, Ohio, Oregon, Rhode Island, and Texas. Sixteen other states including Alabama, California, Colorado, District of Columbia, Iowa, Massachusetts, Maryland, Michigan, Missouri, Mississippi, North Carolina, New Hampshire, Pennsylvania, Virginia, Wisconsin, and Wyoming had the copayment policies in every year through 1996. The rest of the copay states reported having the policies implemented in certain years of the study time frame.

Prescription cap

The number of states with either a presence or an absence of the prescription cap policy seemed to be consistent in every year from the beginning through the end of the study time frame. From 1992 to 1996, 75.5% of the states did not impose the limits on

number of prescriptions that can be reimbursed by the Medicaid programs. Ten states including Arkansas, Florida, Georgia, Mississippi, North Carolina, Nevada, Oklahoma, South Carolina, Texas, and Wyoming had the prescription cap policy implemented in every year through 1996. Notably, only two states reported the changes in this policy variable during the five years of study period. Missouri has withdrawn limits on prescription quantities since 1993, whereas California implemented that policy in 1994. The limits on the reimbursable number of prescriptions in these states ranged from 3 to 6 prescriptions per month.

Drug non-reimbursement rate

State variations in the coverage limits of Medicaid drugs were captured by a variable representing the fraction of non-reimbursed drugs averaged across major drug classes. This study found 84 classes of Medicaid drugs came from the 50 therapeutic classes that were used most in any of the 49 state Medicaid programs. At the national level, these 84 drug classes contributed between 96.4% and 96.9% of all Medicaid prescriptions, and 92 - 95% of total drug expenditures depending on the year. Eighty-eight percent of these 84 classes also appeared among the top 50 drug classes that are ranked by state annual drug expenditures.

The active ingredient, route of administration, and prescription status of Medicaid drugs form the units of analysis for the calculation of the drug non-reimbursement rate. The number of the reimbursed Medicaid drugs averaged across the top 50 classes was about 22 drug products. Table 5.2 presents total number of these unique drug products that were reimbursed by Medicaid in any states for each year.

Table 5.2

Number of Medicaid drug products[a] from the top 50 classes, 1992-1996

	Federal fiscal year				
	1992	1993	1994	1995	1996
PENICILLINS	33	31	29	29	29
CEPHALOSPORINS	33	35	32	32	38
MACROLIDES	18	16	17	18	19
TETRACYCLINES	17	14	12	12	13
FLUOROQUINOLONES	10	10	10	9	9
ANTIMYCOBACTERIALS	12	12	11	12	12
ANTIFUNGALS	10	11	11	11	13
ANTIRETROVIRALS	4	4	5	7	10
HERPES AGENTS	3	2	3	4	5
ANTIMALARIALS	10	10	10	12	12
MISC. ANTIINFECTIVES	18	18	19	19	19
COMBINED MISC. ANTIINFECTIVES	4	4	4	4	4
VACCINES	20	20	1	1	1
ANTINEOPLASTICS	59	66	65	68	77
CORTICOSTERIODS	34	34	31	32	32
ESTROGENS	21	19	20	21	19
CONTRACEPTIVES	17	19	19	19	18
PROGESTINS	7	7	7	7	7
ANTIDIABETICS	34	34	32	32	34
THYROID HORMONES	8	8	7	7	7
CARDIOTONICS	4	4	5	6	6
ANTIANGINALS	12	13	12	11	12
BETA BLOCKERS	16	18	18	18	18
CALCIUM BLOCKERS	11	11	11	11	12
ANTIARRYTHMICS	18	18	18	18	19
ANTIHYPERTENSIVES	63	62	62	65	65
DIURETICS	34	35	36	33	34
ANTIHYPERLIPIDEMICS	9	9	10	10	10
ANTIHISTAMINES	27	29	28	26	30
DECONGESTANTS	20	18	20	22	24
COUGH-COLD-ALLERGY	189	180	164	159	153
ANTIASTHMATICS	66	66	57	59	61

Table 5.2 (Continued)

	Federal fiscal year				
	1992	1993	1994	1995	1996
LAXATIVES	57	54	48	51	50
ANTIDIARRHEALS	19	19	19	20	18
ANTACIDS	26	26	22	20	19
ANTIULCER	43	42	35	38	41
ANTIEMETICS	21	21	22	23	21
GI STIMULANTS	4	5	5	5	5
INTESTINAL ACIDIFIERS	1	1	1	1	1
URINARY ANTIINFECTIVES	19	19	18	17	17
URINARY ANTISPASMODICS	7	7	6	6	6
VAGINAL ANTIINFECTIVES	16	14	15	15	15
GU IRRIGANTS	8	8	8	8	7
ANTIANXIETY	19	19	19	19	19
ANTIDEPRESSANTS	20	22	22	24	24
ANTIPSYCHOTICS	39	38	39	38	38
HYPNOTICS	33	33	29	31	29
STIMULANTS	18	16	17	17	15
MISC. PSYCHOTHERAPEUTICS	4	4	4	4	4
SMOKING DETERRENTS	2	2	2	2	5
COMBINATION PSYCHOTHERAPEUTICS	3	3	2	2	2
NONNARCOTIC ANALGESICS	41	41	38	35	37
NARCOTIC ANALGESICS	58	57	51	53	58
ANTIRHEUMATICS	26	25	26	27	30
ANTIMIGRAINE	10	11	10	12	13
ANTIGOUT	6	6	6	6	6
ANTICONVULSANTS	19	20	21	22	23
ANTIPARKINSONIAN	12	12	12	11	11
MUSCLE RELAXANTS	20	20	18	18	18
VITAMINS	33	33	36	36	37
MULTIVITAMINS	53	49	49	45	47
MINERALS AND ELECTROLYTES	93	99	92	97	96
HEMATOPOIETICS	32	32	32	35	36
ANTICOAGULANTS	9	9	9	10	11
HEMATORHEOLOGICS	1	1	1	1	1

Table 5.2 (Continued)

	Federal fiscal year				
	1992	1993	1994	1995	1996
OPH. ANTIINFECTIVES	9	9	10	10	10
OPH. SULFONAMIDES	2	2	2	2	2
ARTIFICIAL TEARS & LUBRICANTS	4	4	4	4	4
OPH. BETA-BLOCKERS	5	5	5	6	6
OPH. STERIODS	21	21	20	20	20
MIOTICS	11	11	11	10	11
OTIC COMBINATIONS	8	7	7	7	7
THROAT ANTIINFECTIVES	6	7	6	6	7
ACNE PRODUCTS	21	20	18	20	21
TOPICAL ANTIBIOTICS	29	27	25	25	26
TOPICAL ANTIFUNGALS	33	32	31	30	35
TOPICAL CORTICOSTEROIDS	40	40	38	37	37
EMOLLIENTS	10	8	10	9	10
TOPICAL ENZYMES	6	6	7	7	7
SCABICIDES	10	11	9	9	9
MISC. TOPICAL	27	26	26	26	28
DIAGNOSTIC BIOLOGICALS	5	5	2	2	2
CONTRACEPTIVES	3	3	2	2	2
LIQUID VEHICLES	13	13	14	15	16

[a] Drug products with the same prescription status, active ingredient, and route of administration

The non-reimbursed proportion of Medicaid drugs for a given drug class in a state is the ratio of the number of drug products excluded from Medicaid reimbursement in that state to the total number of Medicaid drugs reimbursed by other states for the same class. As stated earlier in Chapter 4, the average of these non-reimbursed proportions in a given state is used as a proxy for drug benefit management restriction associated with drug formulary policy in that state when controlling for total number Medicaid enrollees of the same state. In this study, non-reimbursement rates were averaged across the 84

classes by using arithmetic mean weighted by total number of prescriptions in each class.

The resulting non-reimbursement rates ranged between 15.5% (in Indiana) and 44.7% (in Alaska) in 1992, and between 16.2% (in Pennsylvania) and 39.1% (in Vermont) in 1996. Over time, proportion of Medicaid drugs that were not reimbursed decreased slightly from 29.7% in 1992 to 27.8% in 1996. Variation in the non-reimbursement rates across states within the same year was more prominent (SD: 6.1% in 1996 and 6.8% in 1992) than within the same state.

Five states with the lowest drug non-reimbursement rates over the five-year period were Missouri (16.2 $\pm$ 1.3%), Indiana (16.4 $\pm$ 1.7%), Pennsylvania (17.5 $\pm$ 2.1%), Florida (18.5 $\pm$ 2.0%), and Illinois (18.8 $\pm$ 3.5%). Noticeably, the highest non-reimbursement rates were found in the less populated states including Alaska (39.8 $\pm$ 3.0%), Wyoming (38.1 $\pm$ 2.8%), District of Columbia (37.9 $\pm$ 1.9%), Vermont (37.7 $\pm$ 1.5%), and Delaware (36.9 $\pm$ 3.0%).

5.1.4 Mix of Medicaid drugs

Generic dispensing rate

There are 622 unique drug products (with the same prescription status and the equivalent active ingredient plus route of administration) that come from the top 200 drugs by Medicaid expenditures in any states during 1992-1996. These 622 drugs accounted for 94.5 – 96.0% of the national Medicaid drug expenditures and for 91.7 – 93.2% by prescriptions during the five years of study period. Of the top 200 drugs, 28.1 – 29.3% of them were identified as single source drugs for the whole group and will be

excluded from the calculation of generic dispensing rate because by definition they could not be substituted generically.

Across the 622 equivalent drug entities, counts of generic prescriptions varied from 0 to 100% of the multi-source prescription counts. A state-level variable for generic dispensing rate was calculated by using dollar-weighted average of these generic proportions within this top 200-drug entity subset. The resulting generic dispensing rates ranged between 21.6% (in Oklahoma) and 41.9% (in Idaho) in 1992, and between 42.0% (in Alaska) and 62.8% (in California) in 1996.

Generic drugs were dispensed increasingly in every state Medicaid program. On average, generic dispensing rates increased from 32.6% in 1992 to 51.8% in 1996. Unlike the non-reimbursement rates, variation in generic dispensing rates across states within the same year was relatively low (SD: 3.7% in 1992 and 3.8% in 1996).

Single source drug prescribing rate

Variation in the mix of the reimbursed Medicaid drugs on the other end was captured by proportion of all-source prescriptions filled by single source drugs. The proportion of all-source prescriptions that were prescribed and dispensed for single-source drugs was calculated from the same top 200 subset that used for calculation of generic dispensing rate. The resulting single source drug prescribing rates ranged between 28.4% (in New Hampshire) and 41.4% (in Alaska) in 1992, and between 50.8% (in California) and 61.0% (in Oregon) in 1996.

Cross-sectional observations in California or Alaska indicated that an increase in generic dispensing rate was associated with a decrease in single source prescriptions and

vice versa. Longitudinally, single source drug prescribing rates showed an increasing trend similar to generic dispensing rates. The single source prescribing rate of 33.7% in 1992 increased to 55.9% in 1996 with a relatively low variation across states (SD: 2.3% in 1992 and 2.5% in 1996).

Consistent increases in the state-specific prescription fill rates for generic and single source drugs suggested a market-wide phenomenon. The number of Medicaid prescriptions were increasingly prescribed and filled by the single source drug products with an average annual growth rate of 13.5% during the study period. The average annual growth rate of generic dispensing in the prescriptions of multisource drugs was about 12.4% over the same period. Increases in the rates of generic dispensing and single-source drug prescribing came with the shrinkage of the proportion of Medicaid prescriptions for innovative or branded multi-source drugs.

5.1.5 Medicaid payment basis

Allowable drug ingredient cost

Medicaid payment basis for the ingredient cost of non-MAC drugs and drugs prescribed with 'medical necessary' brands is defined as a percentage of average wholesale price (AWP). During the study period, there are no substantial variations in the basis for drug ingredient cost payment either across states or over time. Thirty-five states (71.4%) did not change the ingredient cost basis until the end of this study. Of these 35 states, 62.9% allowed the ingredient cost basis at least 90% of AWP. The minimum markup of 84.0% of AWP is reported in Rhode Island in 1996, which

decreased from 100% of AWP during the first three years. Other five states including Idaho, Missouri, New York, Pennsylvania, and West Virginia allowed the full 100% AWP amounts as the ingredient cost basis for 1-5 years.

Dispensing fee

In 1992, the dispensing fee that Medicaid programs paid retail pharmacies for dispensing a prescription ranged from $2.00 in Montana to $5.60 in North Carolina. Since then, thirty-three states have not increased the prescription dispensing fee payments through the end of study period. Eighteen states specified the dispensing fees as a range of which the lower bound is used in the model. Overall, the dispensing fee stayed almost constant in terms of the current-year dollar amounts. When adjusted for the economy-wide inflation rates, the dispensing fee decreased over time.

5.2 Estimation of effects on drug expenditures per Medicaid enrollee

The dependent variable *DRUGEXP* (CPI-adjusted dollars of Medicaid drug expenditures) was transformed into natural log scale for two purposes. First, to facilitate an interpretation of the regression coefficients of each explanatory variable with regard to the effect on Medicaid drug expenditures. A regression coefficient on the log *DRUGEXP* is interpreted as the percentage change in the expenditures associated with one unit change in a continuous explanatory variable.[1] Second, distribution of the expenditures

[1] In semilogarithmic equations, the effect of an indicator variable (relative to the reference category) on the percentage change in the dependent variable is equal to $100\times[e^{(\beta - 0.5\mathrm{Var}(\beta))} - 1]$, where β is the regression coefficient, as suggested by Kennedy (1981).

per enrollee in this study is positively skewed (skewness = 0.424, $P < 0.01$). Various functional forms of the expenditures show that the statistical significance of the raw-scale skewness disappeared after taking squared root ($P = 0.11$) or log transformation ($P = 0.35$).

5.2.1 OLS estimates of cross-sectional regressions

Table 5.3 presents the ordinary least squares (OLS) estimates of the effects on drug expenditures per Medicaid enrollee for every yearly data set (N = 49 cross-sectional observations each). Each cross-sectional OLS model was tested whether or not the required assumptions of classical linear regression were hold.

Regression diagnosis

Summary statistics of Cook's distance (Cook, 1977) indicate no single outlier observations that influenced the OLS regression estimates in any particular years. Studentized residuals from the OLS estimates were examined for violation of the normality assumption of the error terms (Shapiro and Wilk, 1965; D'Agostino et al., 1990). The results from each of the five years show no evidence of non-normality of the error terms. Ramsey RESET test (1969) based on a regression of *DRUGEXP* on the originally specified set of explanatory variables and powers of the predicted values (squared, cubic, and the fourth power) does not reveal statistical significance of omitted variable bias. Pregibon's link test based on a regression of *DRUGEXP* on the squared predicted values does not indicate non-linearity of the specified functional form. To test for heteroscedasticity, the error variance functions with respect to the predicted values

(Cook and Weisberg, 1983), and variables representing Medicaid population (Park, 1966; Glejser, 1969) were tested for statistical significance. No violation of the homoscedasticity assumption was found.

The R-squared of the cross-sectional regression ranges from 68.6% (in 1992) to 81.1% (in 1995). The models show a good fit of the data for every year.

Table 5.3

Cross-sectional OLS estimates on log expenditures per Medicaid enrollee (N=49)

	Regression coefficient				
	1992	1993	1994	1995	1996
COPAY (Prescription copayment)	-0.0174	-0.0252	0.0198	-0.0026	0.0091
PRESCAP (Prescription cap)	-0.1685**	-0.2442**	-0.2579**	-0.2651**	-0.2551**
NRR (Non-reimbursement rate)	-0.0173**	-0.0164**	-0.0120**	-0.0091*	-0.0047
GDR (Generic dispensing rate)	0.0028	-0.0037	0.0001	-0.0007	-0.0102
SPR (Single source drug prescribing rate)	-0.0051	-0.0050	-0.0018	0.0053	0.0114
INGCOST (Allowable ingredient cost)	0.0040	0.0015	0.0064	0.0049	0.0262*
DISPFEE (Dispensing fee)	0.0093	-0.0108	-0.0323	-0.1159*	-0.1301*
ENRTOT (Total Medicaid enrollees)	-5.9×10^{-8}*	-3.8×10^{-8}	-4.7×10^{-9}	-1.1×10^{-8}	8.2×10^{-9}
ENRFM (Female enrollee)	-0.0087	-0.0015	0.0028	0.0127	0.0198
ENRAD (AFDC adult enrollee)	-0.0087	0.0001	-0.0047	-0.0032	-0.0128
ENRAG (Aged enrollee)	0.0067	0.0217*	0.0271*	0.0410**	0.0404**
ENRBD (Blind/disable enrollee)	0.0078	0.0117	0.0075	0.0186**	0.0197*
MEDNEED (Drug coverage for medically needy enrollee)	0.0650	0.0514	0.0839	0.0990*	0.1075
MCDMC (Medicaid managed care penetration rate)	-0.0062**	-0.0047*	-0.0033*	-0.0050**	-0.0041*
R^2	0.686	0.707	0.707	0.811	0.734

* $P < 0.05$, ** $P < 0.01$

Effects of restrictive Medicaid drug benefit management policies

The regression coefficients for *COPAY* variable (copayment amount in constant dollars) show the negative sign in certain years (1992, 93, and 95). An association between the copayment policy and Medicaid drug expenditures per enrollee does not reach the statistical significance at 5% level in every year of the cross-sectional data.

An association between the presence of prescription cap policy (*PRESCAP*) and a decrease in the expenditures is highly significant in all of the five years. The magnitude of this relationship is relatively consistent during the last 4 years of the study period. States that implemented the prescription cap policy would have drug expenditures lower by 21.8, 22.9, 23.4, and 22.8% in 1993, 94, 95, and 1996, respectively ($P < 0.01$). This effect (15.7%) is relatively weaker in the year 1992 ($P < 0.01$).

The cross-sectional regressions show the statistical significance in the relationship between *NRR* (non-reimbursement rate) and the Medicaid drug expenditures per enrollee in every year except 1996. The magnitude of this negative association seems to decrease gradually over the years for observations. All other things being equal, a one percentage point increase in the non-reimbursed fraction of Medicaid drugs had the annual expenditures that were lower by 1.7, 1.6, 1.2, and 0.9% in 1992, 93, 94, and 1995, respectively ($P < 0.01$ in 1992-94, $P < 0.05$ in 1995).

Effects of mix of the reimbursed Medicaid drugs

State variations in mix of the reimbursed Medicaid drugs as measured by generic dispensing rate (*GDR*) and single-source drug prescribing rate (*SPR*) are not significantly associated with state variations in the expenditures in any years of the cross-sectional

data.

Effects of Medicaid payment basis

The positive relationship between Medicaid drug expenditures and the allowable drug ingredient cost (*INGCOST*) across states reaches statistical significance only in the last year (1996). A one percentage point increase in the payment basis for drug ingredient costs had 2.6% higher expenditures than other states ($P < 0.05$).

The dispensing fee per prescription (*DISPFEE*) in CPI-adjusted dollar amount is statistically significant only in the last two years. Notably, relationship between *DISPFEE* and drug expenditures becomes more and more negative over time. The regression coefficients change from the non-significant positive in 1992 to non-significant negative in 1993 and 1994 until they reach the statistically significant negative in the last two years.

Effects of Medicaid population

The effect of gender mix of the Medicaid enrollees on drug expenditures per Medicaid enrollee is not significant in any year. Data in 1993-1996 show a statistically significant relationship between Medicaid drug expenditures and fraction of the elderly Medicaid enrollees (*ENRAG*) ($P < 0.01$ in 1995-96, $P < 0.05$ in 1993-94). A one percentage point increase in the proportion of Medicaid elderly increased drug expenditures per enrollee by 2.2, 2.7, 4.1, and 4.0% in 1993, 94, 95, and 96, respectively. The positive effect on drug expenditures is also found in *ENRBD* (proportion of blind/disable enrollees) for the data in the last two years of the study period ($P < 0.01$ in 1995, $P < 0.05$ in 1996). A one percentage point increase in *ENRBD* increased drug

expenditures per enrollee by 1.9 and 2.0% in 1995 and 1996, respectively.

For almost every year except in 1995, states with extended drug benefit provisions to the medically needy enrollees (*MEDNEED*) do not show a statistically significant difference in the per enrollee expenditures from the rest of the states that provided Medicaid drug benefits to only the categorically needy enrollees. An increase in the penetration rate of Medicaid managed care enrollees (*MCDMC*), however, is associated with a decrease in the expenditures per enrollee in every year ($P < 0.01$ in 1992 and 1995, $P < 0.05$ in 1993, 1994, and 1996).

5.2.2 Estimates from pooled cross-sectional time-series regression

Table 5.4 presents the results from Chow Test for structural consistency of parameter estimates in the pooled cross-sectional time-series data of the three models. This study assumes the parameter consistency across 49 time-series for the first pooled model that uses drug expenditures per Medicaid enrollee as the dependent variable. The second and third models that used the expenditures per drug recipient and fraction of the Medicaid drug recipients as the dependent variables pool the data across 47 time-series.

With regards to the consistency of parameter estimates across 5 state panels, the results in relative differences in mean squared errors between the pooled data and sum of the separate cross-sections do not reach statistical significance at 5% level. Therefore, the regression coefficients from each of the five years can be assumed to be constant across the 5 subsets of state panels. A pooled model that combines the cross-sectional observations of state Medicaid programs with 5 year periods is acceptable and there is no

need to include the interaction term between the primary variables of interest with the time period variable in the pooled model.

Table 5.4

Chow Test for structural consistency of parameter estimates

	Dependent variable		
	Drug expenditures per enrollee	Drug expenditures per drug recipient	Drug recipients per 100 enrollees
Pooled data sum square errors	4.7345	3.4652	9266.52
Separate data sum square errors	3.6457	4.1143	10389.01
F-statistic	0.846	0.866	0.560
Model degree of freedom	14	9	9
Number of total observations	245	235	235
P-value	0.77	0.70	0.98

Fixed effect and random effect models

Table 5.5A presents the results from estimations of the five-year pooled data by using fixed effect and random effect models. For the random effect model, fraction of the state-specific random variations, which is indicated by rho constitutes about 76% of the total variations. Breusch and Pagan Lagrangian multiplier test (1980) shows the statistical significance of the random effect within a state ($P < 0.01$). For the fixed effect model, the F-statistic ($F_{(48,188)}=8.26$) indicates that the unobserved state-specific effects are statistically different from zero ($P < 0.01$).

Table 5.5A

Fixed effect and random effect estimates on log expenditures per Medicaid enrollee (N=245)

Full model

	Regression coefficient	
	Fixed effect	Random effect
COPAY (Prescription copayment)	-0.0156	-0.0063
PRESCAP (Prescription cap)	0.0139	-0.1173**
NRR (Non-reimbursement rate)	0.0029	-0.0033
GDR (Generic dispensing rate)	0.0003	0.0003
SPR (Single source drug prescribing rate)	0.0069**	0.0079**
INGCOST (Allowable ingredient cost)	-0.0013	-0.0004
DISPFEE (Dispensing fee)	-0.0242	-0.0643*
ENRTOT (Total Medicaid enrollees)	-4.8×10^{-8}	-1.5×10^{-8}
ENRFM (Female enrollee)	-0.0061	0.0011
ENRAD (AFDC adult enrollee)	-0.0106**	-0.0107**
ENRAG (Aged enrollee)	0.0031	0.0160**
ENRBD (Blind/disable enrollee)	0.0322**	0.0228**
MEDNEED (Drug coverage for medically needy enrollee)	-	0.0773
MCDMC (Medicaid managed care penetration rate)	-0.0016**	-0.0020**
Rho	0.888	0.757

* $P < 0.05$, ** $P < 0.01$

This non-zero variance specific to the cross-sectional units of states contributes approximately 89% of the total variations in observations. The statistically significant non-zero of the unobserved state-specific effects from both fixed effect and random effect

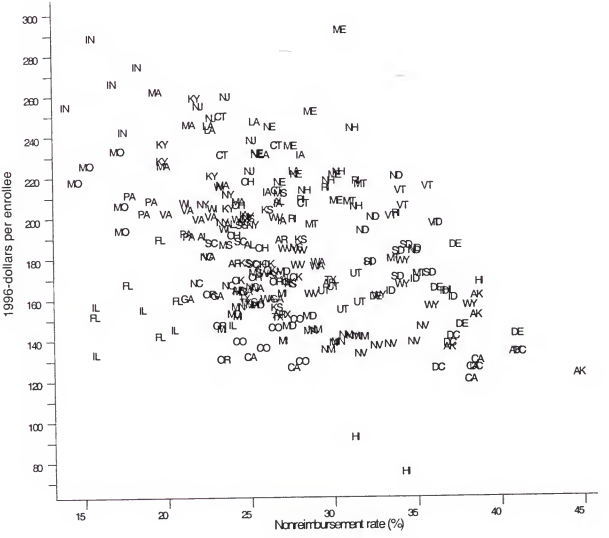
models confirms that distribution of the error term within a state is not independent. Therefore, the classical linear regression estimates for the pooled data are not appropriate for this data set.

The negative relationships between state drug expenditures and two policy variables: *PRESCAP* (the presence of prescription cap policy) and *NRR* (drug non-reimbursement rate) are not statistically significant in the fixed effect estimates from the pooled model. The descriptive statistics of *PRESCAP* show almost no variation in this binary variable over the study time period. As described earlier, only Missouri and California changed their prescription cap policy during the study time period.

The relationship between Medicaid drug expenditures per enrollee and drug non-reimbursement rate during 1992-96 is shown in Figure 5.1. The pooled data show a negative relationship between Medicaid drug expenditures and drug non-reimbursement rate (*NRR*) for the 245 state-year observations. The high expenditure states like Indiana also has a large number of the reimbursed Medicaid drugs (relatively low *NRR*), whereas low expenditure states like the District of Columbia and Alaska have a relatively small proportion of Medicaid drugs. However, there is no systemic variation between these two variables. Specifically, the high expenditure states seem to have a lower degree of restriction with respect to Medicaid drug coverage in every year of observation. Also, there is no explicit downward trend in the expenditure with respect to Medicaid drug coverage within the same state for the low expenditure states.

Figure 5.1

Drug expenditures and drug non-reimbursement rate, pooled data 1992-96



The effect of *COPAY* (change in copayment amounts) on Medicaid drug expenditures per enrollee remains non-significant in both fixed effect and random effect models. From the fixed effect model, state variations in the relative changes of three variables that are significantly associated with the relative changes in the expenditures are *SPR*, *ENRBD*, and *MCDMC*. These variables also show statistically significant effects in the random effect model with the similar magnitudes. Interestingly, the effect of the prescribing rate of single-source drugs (*SPR*) that are not significant in any years of the cross-sectional data is revealed under the pooled model for both fixed and random effects. An increase in the proportion of the prescriptions that were filled by single source drugs by 1% would result in an increase in the Medicaid drug expenditures per enrollee by 0.7% (fixed effect) and 0.8% (random effect).

The Hausman specification test (1978) indicates that the differences between the generalized least squares estimates from the random effect model and the consistent least squares dummy variable estimates from the fixed effect model are statistically significant ($P < 0.01$). The statistically significant effect of *ENRAG* from the random effect model disappears when estimated by the fixed effect model. Another major difference between the random effect and fixed effect models is found in the estimation for *PRESCAP* variable. The random effect model shows the significant negative effect of *PRESCAP* as in the cross-sectional OLS regressions despite the relatively low magnitude of the effect. Under the fixed-effect model, a presence of prescription cap policy does not show a significant relationship with an increase in the expenditures.

This study also runs alternative fixed effect and random effect models without

PRESCAP variable (Table 5.5B). The regression coefficients are similar to those in the full models with all variables. The Hausman test still confirms that the fixed effect estimates are more appropriate than the random effect estimates.

Table 5.5B

Fixed effect and random effect estimates on log expenditures per Medicaid enrollee (N=245) Without *PRESCAP* variable

	Regression coefficient	
	Fixed effect	Random effect
COPAY (Prescription copayment)	-0.0153	-0.0088
NRR (Non-reimbursement rate)	0.0028	-0.0018
GDR (Generic dispensing rate)	0.0003	-0.0002
SPR (Single source drug prescribing rate)	0.0069**	0.0073**
INGCOST (Allowable ingredient cost)	-0.0011	-0.0020
DISPFEE (Dispensing fee)	-0.0240	-0.0721*
ENRTOT (Total Medicaid enrollees)	-4.1×10^{-8}	-2.6×10^{-8}
ENRFM (Female enrollee)	-0.0056	0.0056
ENRAD (AFDC adult enrollee)	-0.0106**	-0.0112**
ENRAG (Aged enrollee)	0.0030	0.0130*
ENRBD (Blind/disable enrollee)	0.0324**	0.0251**
MEDNEED (Drug coverage for medically needy enrollee)	-	0.0883
MCDMC (Medicaid managed care penetration rate)	-0.0016**	-0.0018**
Rho	0.885	0.819

* $P < 0.05$, ** $P < 0.01$

From the pooled data, this study relies on the fixed effect estimates. All else being equal, states with an increase in the single-source drug prescribing rate by 1% would have the drug expenditures per enrollee increased by 0.7% ($P < 0.01$, 95% confidence interval, CI = 0.3 – 1.1%).

The residuals from the fixed effect model were tested for possible violation of the assumptions of non-linearity and heteroscedasticity. The Pregibon's link test and Ramsey RESET test did not indicate significant non-linearity problem. Park tests using regressions of log of the squared residuals on the predicted values and *ENRTOT* did not show statistical significance of heteroscedasticity problem.

5.2.3 Two-stage least squares fixed effect estimates

The three Medicaid policy variables of interest: *COPAY*, *PRESCAP*, and *NRR* were instrumented by a set of the policy determinants suggested in Chapter 3. Two-stage least squares estimate from the fixed effect model is used for this analysis purpose. In the first stage, each of the three endogenous policy variables was predicted by a set of the reduced-form exogenous variables from both the expenditure equation and the endogenous policy equation. Reduced-form variables from the policy equation consist of a set of dummy variables representing the political parties of state governors, state per capita income, federal medical assistance percentage, Medicaid expenditures as a proportion of state general expenditures, state total population, percentage of state population enrolled in managed care, and dummy variables of years. The political ideology variable is dropped from the estimation model because the variable does not

change over time. In the second stage, the three instrumented policy variables are plugged into the expenditure equation along with other covariates.

Table 5.6 presents the results of the two-stage least squares estimates of fixed effect models. The sign of coefficients of two instrumented policy variables: *PRESCAP* and *NRR* become negative as in the cross-sectional regression and random-effect model. However, the effects do not reach statistical significance level at 5%. The effect of the instrumented policy variable: *COPAY* is still not significant as in other prior models.

Table 5.6

Two-stage least squares fixed effect estimates on log drug expenditures per enrollee

	Regression coefficient
COPAY (Prescription copayment)	0.0023
PRESCAP (Prescription cap)	-0.0654
NRR (Non-reimbursement rate)	-0.0012
GDR (Generic dispensing rate)	-0.0010
SPR (Single source drug prescribing rate)	0.0067**
INGCOST (Allowable ingredient cost)	-0.0003
DISPFEE (Dispensing fee)	-0.0304
ENRTOT (Total Medicaid enrollees)	-1.4×10^{-8}
ENRFM (Female enrollee)	-0.0077
ENRAD (AFDC adult enrollee)	-0.0106**
ENRAG (Aged enrollee)	0.0004
ENRBD (Blind/disable enrollee)	0.0350**
MCDMC (Medicaid managed care penetration rate)	-0.0016**

* $P < 0.05$, ** $P < 0.01$

The positive effect of single source drug prescribing rate on drug expenditures remains statistically significant at about the same magnitude as in the single stage fixed effect model ($P < 0.01$). Three other significant control variables including *ENRAD*, *ENRBD*, and *MCDMC* have the comparable effects as in the single stage fixed effect model.

Exogeneity test for state Medicaid policy variables

Results from the expanded regression equation of the expenditures that contains the predicted values of the three policy variables as additional regressors do not show the statistical significance in the regression coefficients. This study cannot reject the hypothesis that state Medicaid drug policies are exogenous.

5.3 Estimation of effects on drug expenditures per drug recipient

As mentioned earlier, variations in state drug expenditures per Medicaid enrollee can be partitioned into two parts. For Medicaid enrollees whose prescriptions were reimbursed by Medicaid at least once in a year, variations in the intensity component of drug expenditures can be captured by the variable representing drug expenditures per drug recipient. The second part indicates the propensity component of drug utilization, which is captured by fraction of the drug recipients among total Medicaid population. Drug expenditures per recipient and drug recipients per 100 enrollees are regressed on two separate sets of explanatory variables from 47 states (excluding Hawaii and Rhode Island) over 5 years. Table 5.7 presents the cross-sectional OLS (N = 47) for the effects on drug expenditures per drug recipient.

Table 5.7

Cross-sectional OLS estimates on log expenditures per drug recipient (N = 47)

	Regression coefficient				
	1992	1993	1994	1995	1996
COPAY (Prescription copayment)	0.0313	0.0101	0.0110	0.0379	0.0326
PRESCAP (Prescription cap)	-0.1291*	-0.2092**	-0.1991**	-0.2007**	-0.1648**
NRR (Non-reimbursement rate)	-0.0098**	-0.0109**	-0.0102**	-0.0100**	-0.0118**
GDR (Generic dispensing rate)	0.0036	-0.0003	-0.0018	-0.0019	-0.0234**
SPR (Single source drug prescribing rate)	0.0045	0.0031	0.0034	0.0140	0.0024
INGCOST (Allowable ingredient cost)	0.0047	0.0129	0.0147*	0.0158*	0.0163
DISPFEE (Dispensing fee)	-0.0258	0.0387	0.0400	0.0554	0.0485
DRUGREC (Total drug recipients)	-8.4×10^{-8}*	-6.2×10^{-8}	-1.3×10^{-8}	-4.9×10^{-8}	-2.6×10^{-8}
MEDNEED (Drug coverage for medically needy enrollee)	0.0454	0.0549	0.0587	0.0830	0.0816
R^2	0.370	0.510	0.501	0.516	0.589

* $P < 0.05$, ** $P < 0.01$

Results from the cross-sectional regressions of the per recipient expenditures on the three restrictive benefit management policies are consistent with those found in the per enrollee expenditure equation. Effects of *COPAY* remain statistically non-significant. The negative effects of *PRESCAP* and *NRR* on the per recipient expenditures are statistically significant in every year. A presence of the prescription cap policy is associated with a decrease in the expenditures per drug recipient by 12.3% in 1992 and by 18.2-19.0% during 1993-95. This negative relationship becomes weaker in 1996

where the expenditures among the Medicaid drug recipients decrease by 15.3%. For the effect of the restriction on Medicaid drug coverage, states that have a 1% lower in the reimbursed fraction of Medicaid drugs would have the expenditures per recipient lower by approximately 1% in each of the five years. The positive relationship between the allowable drug ingredient costs and drug expenditures are statistically significant in 1994-1995.

Table 5.8 presents the estimates from the fixed effect and the random effect models from the same state panel data that were pooled over the five years (N = 235).

Table 5.8

Fixed effect and random effect estimates on log expenditures per drug recipient (N = 235)

	Regression coefficient	
	Fixed effect	Random effect
COPAY (Prescription copayment)	-0.0497**	-0.0311*
PRESCAP (Prescription cap)	0.0301	-0.0947**
NRR (Non-reimbursement rate)	0.0057*	-0.0006
GDR (Generic dispensing rate)	0.0020	-0.0004
SPR (Single source drug prescribing rate)	0.0138**	0.0148**
INGCOST (Allowable ingredient cost)	-0.0001	0.0018
DISPFEE (Dispensing fee)	0.0084	0.0096
DRUGREC (Total drug recipients)	-4.2×10^{-7}**	-6.5×10^{-8}
MEDNEED (Drug coverage for medically needy enrollee)	-	0.0722
Rho	0.966	0.819

* $P < 0.05$, ** $P < 0.01$

The effects of *COPAY* that do not reach statistical significance when estimated either on the per enrollee expenditures or by the cross-sectional regressions becomes statistically significant when estimated on the per recipient expenditures by the pooled cross-sectional time-series regression. An increase in $1 of prescription copayments is associated with a decrease in drug expenditures per recipient by 5.0% ($P < 0.01$, 95% CI = 2.0 – 7.9%) under the fixed effect model and by 3.1% ($P < 0.05$, 95% CI = 0.1 – 6.1%) under the random effect model.

The negative effect of *PRESCAP* on per recipient expenditures is significant in the random effect estimate ($P < 0.01$) but not in the fixed effect model. This is similar to the previous models that use per enrollee expenditures as the dependent variable.

The relationship between the per recipient expenditures and *NRR* is quite counter-intuitive. The fixed effect model shows a significant positive relationship between these two variables ($P < 0.05$).

The positive effect of *SPR* is more pronounced in both the random effect and fixed effect models when considering the expenditure intensity conditional on the Medicaid population who, at least once in a year, was the recipient of Medicaid drugs. An increase in 1% of prescriptions reimbursed with single source drugs would result in an increase in the expenditures per drug recipient by 1.5% by random effect estimate and by 1.4% by fixed effect estimate ($P < 0.01$).

The Hausman specification test still indicates the fixed effect model is more appropriate than the random effect because of the statistically significant difference in the parameter estimates ($P < 0.01$).

5.4 Estimation of effects on number of drug recipients per 100 Medicaid enrollees

Effects of the Medicaid drug benefit management policies *COPAY* and *NRR* on the propensity component of drug utilization are estimated by the regressions using number of drug recipients per 100 Medicaid enrollees as the dependent variable. Table 5.9 presents the estimates based on the cross-sectional data from every state except Hawaii and Rhode Island for each of the 5 years.

Table 5.9

Cross-sectional OLS estimates on drug recipients per 100 Medicaid enrollees (N = 47)

	Regression coefficient				
	1992	1993	1994	1995	1996
COPAY (Prescription copayment)	-2.56	-1.06	1.07	0.64	0.11
NRR (Non-reimbursement rate)	-0.52**	-0.41*	-0.25	-0.30	0.16
ENRTOT (Total Medicaid enrollees)	-5.1×10^{-7}	-1.1×10^{-6}	-9.6×10^{-7}	-1.3×10^{-6}	-1.1×10^{-6}
ENRFM (Female enrollee)	0.55	0.64	-0.05	-0.34	0.08
ENRAD (AFDC adult enrollee)	0.53	0.45	-0.18	-0.38	-0.37
ENRAG (Aged enrollee)	0.73	0.63	0.69	0.78	0.73
ENRBD (Blind/disable enrollee)	0.57	0.56	0.21	0.24	0.53
MEDNEED (Drug coverage for medically needy enrollee)	-0.51	1.49	3.29	3.91	4.03
MCDMC (Medicaid managed care penetration rate)	-0.12	-0.16*	-0.15*	-0.24**	-0.22**
R^2	0.471	0.431	0.407	0.503	0.467

* $P < 0.05$, ** $P < 0.01$

Almost all explanatory variables specified in the cross-sectional regression models do not show the statistically significant association with state variation in the

fraction of Medicaid drug recipients. The regression model explains only 41-50% of the variation in the dependent variable. Both the direction and magnitude of the association between the fraction of drug recipients and *COPAY* or *NRR* variables are not consistent over the years. The effects of *COPAY* are negative only in the first two years but do not reach statistical significance level. The coefficients for *NRR* are negative in almost every year but reach significance level only in the first two years. These significant negative associations disappear when using the pooled data estimated by fixed effect and random effect models (Table 5.10).

Table 5.10

Fixed effect and random effect estimates on drug recipients per 100 enrollees (N = 235)

	Regression coefficient	
	Fixed effect	Random effect
COPAY (Prescription copayment)	0.92	0.97
NRR (Non-reimbursement rate)	-0.17	-0.18
ENRTOT (Total Medicaid enrollees)	-6.5×10^{-6}	-1.4×10^{-6}
ENRFM (Female enrollee)	0.95	0.96*
ENRAD (AFDC adult enrollee)	-0.43**	-0.38**
ENRAG (Aged enrollee)	-0.61	-0.16
ENRBD (Blind/disable enrollee)	-0.06	0.06
MEDNEED (Drug coverage for medically needy enrollee)	-	4.02
MCDMC (Medicaid managed care penetration rate)	-0.13**	-0.14**
Rho	0.884	0.772

* $P < 0.05$, ** $P < 0.01$

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CHAPTER 6

CONCLUSION AND DISCUSSION

The primary purpose of this study was to estimate the effect of state restrictions in drug benefit management policies on the per capita Medicaid drug expenditures over the period from 1992 to 1996. This study used state-level data from forty-nine Medicaid programs. The specific policies to be evaluated are (1) prescription copayment requirements, (2) monthly caps on the number of prescriptions which can be provided to a given recipient, and (3) the proportion of drug products for a given indication that are excluded from Medicaid reimbursement using a formulary or prior authorization. States implement these Medicaid policies with the hope that they will help to slow the rate of growth in Medicaid drug expenditures.

All three of the state policies focus primarily upon managing the utilization of prescribed drugs under Medicaid. Effects of the utilization-targeted restrictions on Medicaid drug expenditures per person were examined. Three separate dependent variables were used in this analysis: (1) drug expenditures per Medicaid enrollee; (2) drug expenditures per Medicaid drug recipient; and (3) the proportion of Medicaid enrollees using one or more prescriptions in a given year. The impact of each of these dependent variables was evaluated with a separate estimation equation.

In the first equation, the effect of the three policies was estimated using the drug expenditure per potential user. This dependent variable was calculated by dividing the total Medicaid drug expenditures in a state by the total number of Medicaid enrollees in

the same state. Because states are different in the number of persons covered by Medicaid in a given year, drug expenditure per Medicaid enrollee rather than total drug expenditure was used.

The second equation used drug expenditure per Medicaid drug recipient as the dependent variable. Since the annual drug expenditure per Medicaid enrollee may fluctuate based on the proportion of Medicaid enrollees who use one or more drugs, this dependent variable examines the drug expenditure only for those Medicaid enrollees receiving one or more prescriptions in a given year. After controlling for variation in the average payment per prescription over time and across states, the assumption was made that the remaining differences in Medicaid drug expenditures per drug recipient were due to differences in utilization. These differences in the utilization are sometimes referred to as the intensity of drug use, that is variation in the number of prescriptions per person per year. The policy effect conditional on Medicaid drug recipients can be assumed to reflect the effect on the number of Medicaid prescriptions when controlled for the factors influencing the pricing component of Medicaid drug expenditures.

The third equation was intended to estimate the impact of state Medicaid policies on the propensity for a Medicaid enrollee to use one or more drugs in a given year. This dependent variable was calculated by the ratio of Medicaid drug recipients using one or more prescriptions in a given year over the total number of Medicaid enrollees in the state for that year.

This concluding chapter consists of five sections. The first section summarizes the major empirical findings in this study. Section two compares the study results with

the previous well-designed studies that examined similar policy issue. Implications for public policy are discussed in the third section. The fourth section discusses the major limitations of the study. Future research needs are described in the final section.

6.1 Summary of major findings

Findings from each of the eight research hypotheses, proposed in Chapter 3, are discussed below.

6.1.1 Copayment effect on proportion of Medicaid enrollees as drug recipients

The first hypothesis is: H_1 – A state that uses a higher amount of copayment per prescription will have a lower number of drug recipients in proportion to total number of Medicaid enrollees. This hypothesis is intended to evaluate the degree to which the copayment amount influenced some proportion of Medicaid enrollees to shift from use of one or more prescriptions to use of no prescriptions. When this hypothesis was evaluated by the cross-sectional data and the pooled time-series data, no statistically significant relationship was found between the amount of copayment and the number of drug recipients proportional to the total number of Medicaid enrollees.

Specifically, implementation of a new, or increased, copayment amount per prescription was not associated with variation in the proportion of Medicaid enrollees receiving one or more prescriptions across states or over time. The lack of a significant effect from higher copayment amounts appears to suggest that if every Medicaid enrollee had a similar need for prescription drugs, the copayment policy would rarely cause the

Medicaid beneficiary to forgo *any* Medicaid drugs in a year.

This study was limited to measurement of the effect of copayment at the aggregate level for each state and time period. Analysis of this issue at the patient level may provide a different finding. In fact, a study using patient-level data (Stuart and Zacker, 1999) found that the copayment reduced the likelihood that Medicaid enrollees would fill any prescriptions during the year. Another explanation for variation in the impact of copayments on proportion of Medicaid enrollees who use one or more prescriptions may hinge on the type of drug needed. While one can understand why some Medicaid enrollees who need a discretionary drug (i.e., a cough suppressant for a viral cold) would decide not to fill their prescription because of the copayment amount, it would be hard to imagine even a Medicaid enrollee forgoing an essential, life-saving prescription (i.e., an epilepsy medication) because of a $1 copayment amount. For those few patients whose only drug need during a year is a discretionary drug, they may not get that prescription filled due to the copayment policy as Stuart and Zacker (1999) found. Neither this study, nor the Stuart and Zacker (1999) study classified prescriptions as discretionary or essential and neither study controlled for this possible effect.

6.1.2 Copayment effect on Medicaid drug expenditure per drug recipient

Copayments are implemented by states with the intent of introducing some degree of consumer cost sharing. This cost-sharing is intended to limit utilization to appropriate and necessary use of prescription drugs. This cost-sharing by the patient (or the pharmacy, when the patient does not pay) also results in cost-shifting a portion of the

prescription payment from the state Medicaid program to the patient (and sometimes to the pharmacy).

As stated in the second hypothesis (H_2), a state that uses a higher amount of copayment per prescription will have a lower Medicaid drug expenditure per drug recipient. A change in the prescription copayment amount was found to have a statistically significant negative relationship with the Medicaid drug expenditure per drug recipient. Other Medicaid policy and state-related variables that could influence the drug expenditure per drug recipient were controlled, so that this effect is considered to be independent of other factors.

This study found that when a state increases its amount of copayment by one dollar, the drug expenditure per drug recipient will decrease approximately 5%. This finding is thought to reflect a decrease in drug use intensity (prescriptions per drug recipient) due to the amount of the copayment. Although this study did control for several factors that could influence the average payment per prescription (dispensing fee, drug ingredient cost allowance, single source drug prescribing rate, and generic dispensing rate), the study was not able to control for differences in the proportion of recipients who did not pay the copayment. The variation in proportion of recipients not paying the copay, however, was assumed to be randomly distributed.

The magnitude of this copayment effect should be interpreted as the upper bound because Medicaid does not allow pharmacies to be reimbursed for any uncollected copayment amount. A reduction in Medicaid drug expenditures in a state that adopts, or increases, a copayment amount will come from three sources. First, these will be some

degree of reduction in the number of prescriptions filled per Medicaid drug recipient. Second, there will be a cost-shifting of the amount of the copayment from the state to the drug recipient, or to the pharmacy if the drug recipient cannot pay the copayment.

6.1.3 Copayment effect on Medicaid drug expenditure per Medicaid enrollee

The third hypothesis is: H_3 – A state that uses a higher amount of copayment per prescription will have a lower Medicaid drug expenditure per Medicaid enrollee. When this hypothesis was evaluated by the estimation equation, a change in the prescription copayment amount was not found to have a statistically significant relationship with the Medicaid drug expenditure per Medicaid enrollee. In the pooled time-series analysis, a negative association between a change in the copayment amount and the drug expenditure per Medicaid enrollee was found but the association was not statistically significant. Other variables that could influence the drug expenditure per Medicaid enrollee were controlled, although no significant relationship was found.

While the copayment amount did have a significant relationship with the drug expenditure per drug recipient, no such relationship was found when examining drug expenditure per Medicaid enrollee. One explanation for this difference is the fact that the proportion of Medicaid enrollees that were drug recipients was in the range from 59 to 63% of the total Medicaid enrollees during the study period. The second dependent variable (drug expenditure per Medicaid enrollee) probably dilutes the same total amount of drug expenditures by adding to the denominator about 40% of the total Medicaid population who did not have any Medicaid prescriptions filled during the year.

6.1.4 Prescription cap effect on Medicaid drug expenditure per drug recipient

The prescription cap policy in this study is the policy that fixes the maximum number of prescriptions that can be filled for a Medicaid drug recipient within a given period, usually in a month. As stated in the fourth hypothesis (H_4), a state that places a limit on the number of prescriptions covered per month per drug recipient will have a lower Medicaid drug expenditure per drug recipient. All else being equal, a presence of the prescription cap in a state is statistically associated with 12-19% (depending on the year of observation) lower in the expenditures per drug recipient compared with the state with an absence of such a policy.

Conclusion regarding this negative relationship is based on the results from the analyses of the cross-sectional data for every year. From the pooled time-series analysis, the random effect model also reveals the statistically significant findings but with a lesser degree of the negative relationship. However, the fixed effect model of the pooled data does not show the statistical significance of the effect of this policy.

Differences in the findings can be explained by the underlying assumptions of the three estimation models. Unlike the cross-sectional analysis that assumes the independent distribution in the observation across states, the pooled model in this study is intended to capture systematic variation in the temporal change from the state mean. The random effect and the fixed effect estimates are different in the assumptions regarding the unobserved temporal variation (i.e., disturbance) associated with a state. The random effect model assumes the state disturbance to be randomly distributed and discounts the state mean with variance fraction associated with the disturbance terms. The fixed effect

model assumed the disturbance to be conditional on the state and contributes all of the disturbances to the state mean. Because there was a change in the prescription cap policy variable in only Missouri and California during the study period, variation in the temporal changes from the state mean becomes relatively small, especially in the fixed effect model.

6.1.5 Prescription cap effect on Medicaid drug expenditure per Medicaid enrollee

The fifth hypothesis is: H_5 – A state that places a limit on the number of prescriptions covered per month per drug recipient will have a lower Medicaid drug expenditure per Medicaid enrollee. This study found the significant negative relationship between the prescription cap policy and Medicaid drug expenditure per Medicaid enrollee. Based on the cross-sectional data during 1993-1996, states that implement the prescription cap policy will have 22-23% lower in the expenditures per Medicaid enrollee than states that do not have such a policy. For the data in 1992, magnitude of the relationship is relatively smaller (19%).

6.1.6 Effect of drug exclusion from Medicaid reimbursement on proportion of Medicaid enrollees as drug recipients

The sixth hypothesis is: H_6 – The proportion of Medicaid enrollees who receive one or more prescriptions in a given year is not related to the proportion of drugs restricted in a state. In this study, state variation in the Medicaid drug coverage restriction was captured by drug non-reimbursement rate that represents proportion of

drugs excluded by states from Medicaid reimbursement among the top 50 therapeutic classes, which were used most in any states during the study period.

An association between variation in the drug non-reimbursement rate and the varying fraction of drug recipients in this study is ambiguous. The negative relationship between these two variables is statistically significant for the cross-sectional data only in the first two years. States that exclude drugs in the top 50 therapeutic classes from Medicaid reimbursement more than other states by 1% will have proportion of Medicaid enrollees who use one or more Medicaid prescriptions lower than the other states by 0.4-0.5%. However, this relationship becomes statistically non-significant for the rest of the study period. Neither random effect nor fixed effect estimates in the pooled time-series models show the significant relationship of the relative changes in these two variables.

6.1.7 Effect of drug exclusion from Medicaid reimbursement on Medicaid drug expenditure per drug recipient

The seventh hypothesis is H_7 – A state that has a higher proportion of drugs restricted (by formulary or prior authorization) will have a lower Medicaid drug expenditure per drug recipient. This study found that if an implementation of the restrictive formulary resulted in a lower proportion of the Medicaid drugs reimbursed by a state, the drug expenditure per drug recipient in that state would be lower than in the state that reimbursed more Medicaid drugs in the same therapeutic class.

The statistically significant negative relationship between the drug non-reimbursement rate and Medicaid drug expenditure per drug recipient is found in every

year of the cross-sectional observation. States that exclude more drugs from Medicaid reimbursement than other states by 1% will have the expenditure per drug recipient lower than the other states by a comparable proportion of 1%.

The pooled time-series analysis does not show the significant negative relationship between the drug non-reimbursement rate and Medicaid drug expenditure per drug recipient. In the fixed effect model, the statistically significant positive relationship of the relative changes in these two variables seems to be counter-intuitive if the exclusion of drugs in a given therapeutic class from Medicaid reimbursement is interpreted as the expenditure-driving factor. It is more understandable that an increase in Medicaid drug expenditures per drug recipient in a state will result in an increased proportion of drugs excluded from Medicaid reimbursement in that state.

6.1.8 Effect of drug exclusion from Medicaid reimbursement on Medicaid drug expenditure per Medicaid enrollee

The eighth hypothesis is H_8: A state that has a higher proportion of drugs restricted (by formulary or prior authorization) will have a lower Medicaid drug expenditure per Medicaid enrollee. This study found the statistically significant effect of drug exclusion from Medicaid reimbursement on the per enrollee expenditure when analyzed by the cross-sectional regression. States that have a non-reimbursement rate for Medicaid drugs greater than other states by 1% will have 0.9-1.7% lower in the drug expenditures per Medicaid enrollee. This negative relationship decreases over time and does not reach the statistical significance level in the last year of the study period.

The pooled time-series analysis does not show the systematic relationship of the variation in the relative changes between these two variables. First, there might be too little temporal variation in the drug non-reimbursement rate within the same state. A scattered plot seems to show that the high expenditure states have a relatively low fraction of the non-reimbursed drugs in every year of observations. The low expenditure states show a relatively high degree of the drug coverage restriction in every year.

Another explanation is that there might be certain state-specific determinants of the expenditures that are correlated with the drug non-reimbursement rate but are not observed in the cross-sectional data. The state-fixed effect in the pooled data adjusts for this omitted variable bias. The possibility that the state policy decision is determined simultaneously with the per enrollee expenditures cannot be detected.

6.1.9 Non-hypothesized relationship

Mix of the reimbursed drugs

Whereas the effect from the relative change in the non-reimbursement portion of Medicaid drugs is negligible, the temporal change in the mix of the reimbursed drugs has a major impact on the Medicaid drug expenditures. Specifically, this study found a strong positive relationship between market introduction of single-source drugs and the Medicaid drug expenditure per person. The single source drug prescribing rate among the top 200 high expenditure drugs, averaged across states, increased from 33.7% in 1992 to 55.9% in 1996. This study found that an increase in the proportion of Medicaid prescriptions that are prescribed and filled by the patent-protected drugs by 1% will result

in an increase in the drug expenditure per Medicaid enrollee by 0.7%. For the Medicaid drug recipients, the effect on the Medicaid drug expenditure increases to 1.4%.

During the same period, fraction of Medicaid prescriptions for the off-patent drugs that were dispensed or substituted by generic drugs increased from 32.6% to 51.8%. However, this study did not find a significant economic impact of an increase in the generic dispensing rate for this multi-source subset of the top 200 Medicaid drugs.

Medicaid managed care

The negative association between the penetration of Medicaid managed care and the drug expenditure per Medicaid enrollee as well as the fraction of Medicaid drug recipients is revealed in every estimation equation. An inclusion of the Medicaid managed care variable is to account for the fact that data on the denominator of the dependent variables include both fee-for-service and managed care enrollees whereas the numerator is reported for drug payments and drug recipients in the fee-for-service sector only. The decreases in the per enrollee expenditures and the drug recipient fraction probably result from the fact that, in the states with increased managed care penetration, there were fewer potential users left in the fee-for-service sector. This would result in a decreased expenditure if Medicaid enrollees in fee-for-service sector and managed care had a comparable need in Medicaid prescriptions. The other explanation is that the sicker individuals tend to seek an enrollment in the managed care where there is often less degree of restriction on Medicaid drug benefits.

Medicaid eligibility status

As anticipated, this study found the significant positive association between the

per enrollee expenditures and the aged enrollees as well as the blind/disable enrollees. States that have the fraction of the aged enrollees higher than other states by 1% will have 2-4% higher in the Medicaid drug expenditure per enrollee. However, the significant association is not found in the first year of study period. This cross-sectional analysis showed a significant association for the blind/disable enrollees for the data only in the last two years. The relationship for the Medicaid enrollees with blind and disability status is more noticeable when using the pooled time-series analysis that can capture the relative increase in the blind/disable fraction over time. On average, the fraction of aged enrollees decreased slightly from 11.2% in 1992 to 10.4% in 1996. Fraction of Medicaid population eligible under the blind/disable status increased from 13.8% to 16.3% during the same period. Also, a decrease in the fraction of AFDC-adult enrollees is found to be associated with an increase in the Medicaid drug expenditure per Medicaid enrollee.

6.2 Comparison with related studies

As mentioned earlier, the present study attempted to control for variation in the pricing component of Medicaid drug expenditures. Factors influencing average payment per prescription: drug ingredient cost allowance; dispensing fee; and mix of the reimbursed drugs were included in the estimation models. The independent effect on the per recipient expenditures found in the present study is assumed to reflect the effect on intensity of Medicaid drug use.

Data from this study reveal the maximum copayment amount is $3.00. If a state required the Medicaid drug recipients to pay at this maximum amount, the Medicaid drug

expenditures per drug recipient would decrease by approximately 15%. This magnitude of the copay effect applied to the utilization intensity is similar to the findings from an analysis of a national representative survey of the dual Medicare-Medicaid eligible population in 1992 by Stuart and Zacker (1999).

Stuart and Zacker (1999) reported the number of filled prescriptions in the copay states was lower than the non-copay states by 15.5%. The major effect of the copayment was found in a reduction in the likelihood that the Medicaid enrollees would fill any prescriptions during the year. The difference in prescription counts for the Medicaid drug recipients between the copay and the non-copay states was much smaller. This result is not consistent with the findings from the present study. During the study period, average fraction of the Medicaid drug recipients using one or more prescriptions is about 59-63%. It is possible that among the 37-41% of Medicaid enrollees who were not the drug recipients, several of them might not have a need for the prescription drugs at all and, consequently, are not the potential users in a given year. In addition, Stuart and Zacker (1999) found that the recipient did not pay the copayment amount for about 30% of the prescriptions reimbursed in the copay state. The magnitude of this uncollected copayment signals the exemption learned by Medicaid enrollees that can weaken the anticipated effect of the copayment policy.

Magnitude of the association between the prescription cap policy and Medicaid drug expenditures per person from the state-level data in the present study is comparable to a prior study using the time-series analysis of person-level data. The present of prescription Soumerai et al. (1987) reported a 38% decrease in the expenditures for the

multiple-drug users and a 19% decrease for the rest of drug users in a state that introduced the prescription cap policy. Regarding the effect on the intensity of drug use, this previous study found a 46% decrease in the number of prescriptions per recipient for the multiple-drug users and a 17% decrease for the other drug users. Unfortunately, the aggregate data used in the present study did not allow for subgroup analyses that could separate the policy impact on the high-use subgroup from the rest.

Two previous pooled time-series analyses estimated the effect of the restrictive drug formulary policy on Medicaid drug expenditures before OBRA90 went into effect. Moore and Newman (1993) using the state panel data in 1985-89 reported that a presence of the formulary restriction was associated with a 13.4% decrease in Medicaid drug expenditures per capita. The second study (Ross-Degnan et al., 1993) using the data in 1980-90 found an association between the presence of the formulary and a 10.2% decrease in drug expenditures per recipient.

In the present study, the variation in drug non-reimbursement rate across states in terms of the standard deviation was between 6.1% in 1996 and 6.8% in 1992. States that have the drug non-reimbursement rate higher than other states by one standard deviation will have Medicaid drug expenditures per drug recipient lower by approximately 6-7%.

The pooled time-series regression in the present study shows a positive relationship between the single source drug prescribing rate and drug expenditures per Medicaid enrollee and per drug recipient. Newly approved drug products marketed by drug manufacturers are called single source drugs because of the patent protection on market exclusivity. The penetration pattern of the patent-protected, single source drugs

in Medicaid prescriptions seems to be a nation-wide phenomenon. This study found an increasing number of Medicaid prescriptions that were filled by single source drugs (an average annual growth rate of 13.5% during the study period). There is also an increasing trend in the fraction of the Medicaid prescriptions for multi-source drugs that were filled by the generic drugs (an annual average growth rate of 12.4%). However, the effect of an increase in the generic dispensing rate on a decrease in Medicaid drug expenditures was not found in this study.

The prices of single source drugs typically are much higher than the price of close competitors that are off-patent brands and generic drugs. The average Medicaid payment per prescription of single source drugs has increased substantially from $43.44 in 1992 to $72.89 in 1998. The payment rate for generic drugs was much lower and increased slightly from the average of $8.38 to $12.92 over the same period (Schondelmeyer SW, personal communication). A study by Sherman et al. (1999) reveals a similar finding on factors affecting the growth in prescription drug expenditures in the nation-wide market.

Sherman et al. (1999) analyzed the Scott-Levin Company's Source Prescription Audit database, which is a national sample of retail prescription drug sales and volume. This unpublished study revealed an increasing trend in the penetration rate of generic drugs by units dispensed from 40% in 1993 to 44% in 1997. However, the market share of generic drugs by dollar sales decreased gradually from 11% to 8% over the same period. The same study also found that an increase in prescription drug spending over time is driven mostly (64%) by an increase in the average product cost per prescription from the more costly new single source drugs.

branded drug industry. Some of the newly marketed drugs with patent-protected market exclusivity status are not totally new chemical entities. For example, the pharmaceutical industry can use dosage regimen modification from an existing chemical entity to extend market exclusivity of a drug product once its original patent status is expired. This tactic is known as the "ever-greening" process. Once the drug with this modified dosage form is launched to the market, it is protected under the newly applied patent. The product is automatically deemed a single source drug that cannot be generically substituted. An increase in generic dispensing rate found in this study comes with the shrinkage of the prescriptions of the branded multi-source drugs for the same chemical entity.

Market promotion of new drug products often focuses on individual health care providers. In addition, a recent change in the FDA regulation regarding direct-to-consumer advertising has contributed to an increase in the use of the new drug products.

Under the federally mandated legislation that prohibited exclusion of the drug products under rebate agreement from Medicaid reimbursement, states should focus on tailoring their policies that would increase incentives for using the off-patent drugs that allow for generic substitution. An existing generic drug-related policy that aims for the cheaper payment rate by itself is limited in scope. The generic substitution policy is applicable only to the prescriptions that are written for multi-source drugs and are not specified that a brand is medically necessary. Reimbursement basis for Medicaid drugs is not necessarily subject to the generic prices (in the MAC lists) because all of the single-source drugs and some multi-source drugs are the non-MAC drugs. The empirical findings in this study suggest that it is difficult to curb the growth in Medicaid drug

expenditures unless states implement an incentive to facilitate the use of cheaper drug products.

6.4 Limitations

Data on the drug expenditures in this study came from the gross Medicaid payments before subtraction of the rebate amounts received from drug manufacturers. This study did not evaluate the policy effect on the net-of-rebate Medicaid drug payments. The drug rebate schedule is typically specified according to patent status of Medicaid drugs and whether the drug is marketed by the innovative or non-innovative firms. Because the estimation model in this study included the variables that can capture the penetration of generic and single-source drugs in Medicaid prescriptions, the result based on the gross payments in this study as compared with the net-of-rebate payments should be robust.

This study does not explicitly define a variable to capture state variations in drug prior authorization process. Drugs with prior authorization requirement are often the same drug products that are excluded from Medicaid reimbursement by the restrictive formulary. The drug non-reimbursement rate variable used in this study is expected to reflect the final results from an implementation of the formulary exclusion and the prior authorization process.

Because the data in this study were not observed at the individual beneficiary level, this study suffers from several inherent limitations. First, this study does not directly examine the policy effects on the intensity of use in terms of prescriptions for an

individual Medicaid drug recipient. The available state-level data on number of the reimbursed prescriptions are incomplete. An imputation for the missing data might not be appropriate if it is to be used as the dependent variable. In this study, the intensity component of the expenditures per drug recipient is used as a proxy in the estimation models that have been partly controlled for the variation in the Medicaid payment rate per prescription.

Second, certain prior studies have identified an unintended effect of the restrictions in Medicaid drug benefit management policies on increased total healthcare costs. An increased use of other medical alternatives might lead to an increase in Medicaid payments for total healthcare. This study is not able to examine this problem. It is difficult to define relevant alternatives of the restricted drug products and to estimate the related healthcare costs without observing the individual level effects.

With regard to the omitted variable bias problem, there is no direct adjustment for the differences in case mix in the estimation models. This study used the reported Medicaid enrollment status as a proxy for the state variations in the underlying need of prescription drugs. As long as there is no correlation between the policy variables of interest and the underlying health care needs, incomplete control for the case mix is not a serious issue for the internal validity of this study.

This study assumes that the major influences on Medicaid drug expenditures are state policy and patient decision on filling the Medicaid prescription as a response to the policy. Variations in the practice of health care providers, particularly prescribing patterns of physicians and dispensing patterns of pharmacies are not directly captured in

the estimation models. This problem is mitigated to some degree by the use of variables that can capture the mix of the reimbursed Medicaid drugs.

This study focuses on state variations in the expenditures of the Medicaid fee-for-service recipients. As managed care organizations have increasingly become involved in the provision of Medicaid services in certain states, an analysis that relies on the state-reported data will become cumbersome. This study partly takes into account of any spillover effects from the managed care sectors by including a variable representing Medicaid managed care penetration rate in the estimation models.

In summary, except for the limitations due to the scope of this study, other limitations would not greatly jeopardize the internal validity of the study results.

6.5 Future research recommendation

Findings of this study suggest that Medicaid drug expenditures are affected by the changes in the utilization behavior of a Medicaid eligible individual as a response to the state decision to impose the utilization-targeted restrictions. However, physicians and pharmacists have a major influence on deciding whether to prescribe or dispense and which drug products to prescribe or dispense in order to accommodate the state enforced policies. Future research should include the variables that can capture the underlying practice variations of health care providers.

The decision to use or not to use certain types of drug products is also facilitated by availability of the alternatives. The empirical findings from this study suggest that among other things, mix of the reimbursed Medicaid drugs plays an important role. The

market intervention by the pharmaceutical industry seems to be a nation-wide phenomenon, which might not be able to be detected by the cross-sectional observations across states. The future research should at least be able to capture the variations in these supply-side determinants by the temporal observations.

This study also found a concentration of Medicaid drug spending in certain drug classes and drug products. Future research should focus on whether drug benefit management policies have differential impacts on different classes of drugs by focusing more on certain high-impact drug classes. The lack of person-level data analysis can be furnished by the state-level prescription data if available.

In an explanation of the state decision to impose restrictions on Medicaid drug reimbursement, the approach used in this study is not able to identify the significant state policy determinants. Research issue on the endogenous state Medicaid policy is worth to be further explored.

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APPENDIX A

Comparative Statics of the Demand for Prescription Drugs

1. Effects of baseline health status

$$\frac{dM^*}{dH^0} = \frac{\begin{vmatrix} U_1 f_{MH^0} + U_{11} f_M f_{H^0} & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{TH^0} + U_{11} f_T f_{H^0} & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_{H^0} & U_{12} f_T & U_{22} & -1 \\ 0 & -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{(U_1 f_{MH^0} + U_{11} f_M f_{H^0})|D_{11}|}{|H|} + \frac{(U_1 f_{TH^0} + U_{11} f_T f_{H^0})(-1)|D_{21}|}{|H|} + \frac{U_{12} f_{H^0} |D_{31}|}{|H|}$$

$$|D_{21}| = \begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_{12} f_T & U_{22} & -1 \\ -w & -1 & 0 \end{vmatrix} =$$

$$-(w\tau + p)[(-1)U_{12} f_T - (-w)U_{22}] + (-1)(-1)[(-1)(U_1 f_{MT} + U_{11} f_M f_T) - (-w)U_{12} f_M]$$

$$|D_{31}| = \begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ -w & -1 & 0 \end{vmatrix} =$$

$$-(w\tau + p)[(-1)(U_1 f_{TT} + U_{11} f_T f_T) - (-w)U_{12} f_T] + (-w)(-1)[(-1)(U_1 f_{MT} + U_{11} f_M f_T) - (-w)U_{12} f_M]$$

In the first term, $|D_{11}|$ is the principal minor of $|H|$ with order 2. It has a positive sign which is opposite to the negative sign of the denominator $|H|$. The first argument of the numerator is negative, given $f_{MH}{}^0 < 0$. Hence, the first term is positive.

In the second term, $|D_{21}|$ has a positive sign, assuming that $U_{12} < 0$ and $f_{MT} < 0$. The first argument of the numerator is negative, given ${f_{TH}}^0 < 0$. Hence, the second term is negative.

The sign of $|D_{31}|$ in the third term is ambiguous because the first argument is negative which is opposite to the positive sign of the last argument. Hence, $\frac{dM^*}{dH^0}$ has indeterminate sign.

2. Effects of endowed income

$$\frac{dM^*}{dY} = \frac{\begin{vmatrix} 0 & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ 0 & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ 0 & U_{12} f_T & U_{22} & -1 \\ -1 & -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{(-1)(-1)|D_{41}|}{|H|}$$

$$= \frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_T & U_{22} & -1 \end{vmatrix}}{|H|}$$

The denominator $|H|$ has a negative sign according to the required second-order condition.

The sign of the numerator, however, is ambiguous because of the unsignable cross-partial terms: U_{12} and f_{MT}. Hence, $\frac{dM^*}{dY}$ has indeterminate sign.

Given that health is not inferior for consumption and medical inputs like prescription drugs are not the inferior inputs for the production of health, M would be a normal good, Hence, $\frac{dM^*}{dY} > 0$.

3. Effects of prescription price

$$\frac{dM^*}{dp} = \frac{\begin{vmatrix} \lambda & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ 0 & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ 0 & U_{12} f_T & U_{22} & -1 \\ M & -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{\lambda |D_{11}|}{|H|} + \frac{M(-1)|D_{41}|}{|H|}$$

$$= \lambda \frac{\begin{vmatrix} U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_T & U_{22} & -1 \\ -w & -1 & 0 \end{vmatrix}}{|H|} - M \frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -(w\tau + p) \\ U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ -(w\tau + p) & -w & -1 \end{vmatrix}}{|H|}$$

The numerator of the first term ($|D_{11}|$) is the principal minor of $|H|$ with order 2. It has a positive sign which is opposite to the negative sign of the denominator $|H|$. Hence, the first term which represents substitution effect will have a negative sign. People

would like to substitute other health-improving alternatives for prescription drugs as a response to an increase in prescription price.

The second term is correspondent to the pure income effect which has a positive sign according to the previous proposition. Hence, the second term is negative when multiplied by -*M*. An increase in prescription price would make people feel that they have less money to spend for prescription drugs.

Hence, $\frac{dM^*}{dp} < 0$. The demand for prescription drugs should fall as a response of an increase in prescription price.

4. Effect of time in obtaining prescription drugs

$$\frac{dM^*}{d\tau} = \frac{\begin{vmatrix} \lambda w & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ 0 & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ 0 & U_{12} f_T & U_{22} & -1 \\ wM & -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{\lambda w |D_{11}|}{|H|} + \frac{wM(-1)|D_{41}|}{|H|}$$

$$= \lambda w \frac{\begin{vmatrix} U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_T & U_{22} & -1 \\ -w & -1 & 0 \end{vmatrix}}{|H|} - wM \frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -(w\tau + p) \\ U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ -(w\tau + p) & -w & -1 \end{vmatrix}}{|H|}$$

The numerator of the first term ($|D_{11}|$) is the principal minor of $|H|$ with order 2. It has a positive sign which is opposite to the negative sign of the denominator $|H|$. Hence, the first term which represents substitution effect will have a negative sign. An increase in time in obtaining prescription drugs would increase the opportunity cost of prescription drugs ($w\tau$), then people would like to substitute other health-improving alternatives for prescription drugs.

The second term is pure income effect which has positive sign, as proposed previously. This term becomes negative when multiplied by -wM. An increase in time in obtaining prescription drugs would make people feel that they have less money to spend for prescription drugs.

Hence, $\dfrac{dM^*}{d\tau} < 0.$

5. Effects of hourly income

$$\frac{dM^*}{dw} = \frac{\begin{vmatrix} \lambda\tau & U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ \lambda & U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ 0 & U_{12} f_T & U_{22} & -1 \\ -(24 - T^0 - \tau M) & -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{\lambda\tau|D_{11}|}{|H|} + \frac{\lambda(-1)|D_{21}|}{|H|} + \frac{-(24 - T^0 - \tau M)(-1)|D_{41}|}{|H|}$$

=

$$\lambda\tau\frac{\begin{vmatrix} U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_T & U_{22} & -1 \\ -w & -1 & 0 \end{vmatrix}}{|H|} - \lambda\frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_{12} f_T & U_{22} & -1 \\ -w & -1 & 0 \end{vmatrix}}{|H|}$$

$$+ (24 - T^0 - \tau M)\frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_M & -(w\tau + p) \\ U_1 f_{TT} + U_{11} f_T f_T & U_{12} f_T & -w \\ U_{12} f_T & U_{22} & -1 \end{vmatrix}}{|H|}$$

The numerator of the first term ($|D_{11}|$) is the principal minor of $|H|$ with order 2. It has a positive sign which is opposite to the negative sign of the denominator $|H|$. The first term has a negative sign. This indicates that an increase in wage rate will result in an increase in opportunity cost for obtaining prescription drugs ($w\tau$), then people would like to substitute other health-improving alternatives for prescription drugs.

The third term has a positive sign as previously proposed. An increase in wage rate would make people feel like they have more money to purchase medical inputs in order to invest in health. Hence, the first and the third term have the opposite signs.

The sign for the second term is ambiguous because of the unsignable cross-partial terms: U_{12} and f_{MT}. Hence, $\frac{dM^*}{dw}$ has indeterminate sign.

6. Effects on time spent for health improvement

6.1 Effects of the endowed income

$$\frac{dT^*}{dY} = \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & 0 & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & 0 & U_{12} f_T & -w \\ U_{12} f_M & 0 & U_{22} & -1 \\ -(w\tau + p) & -1 & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{(-1)|D_{42}|}{|H|}$$

$$= (-1)\frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{22} & -1 \end{vmatrix}}{|H|}$$

The denominator $|H|$ has a negative sign according to the required second-order condition.

The sign of the numerator, however, is ambiguous because of the unsignable cross-partial terms: U_{12} and f_{MT}. Hence, $\frac{dT^*}{dY}$ has indeterminate sign.

Given that health is not inferior for consumption and leisure time is not an inferior input for the production of health, T would be like a normal good, Hence, $\frac{dT^*}{dY} > 0$.

6.2 Effects of the prescription price

$$\frac{dT^*}{dp} = \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & \lambda & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & 0 & U_{12} f_T & -w \\ U_{12} f_M & 0 & U_{22} & -1 \\ -(w\tau + p) & M & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{\lambda(-1)|D_{12}|}{|H|} + \frac{M|D_{42}|}{|H|}$$

$$=$$

$$-\lambda \frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{22} & -1 \\ -(w\tau + p) & -1 & 0 \end{vmatrix}}{|H|} + M \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{22} & -1 \end{vmatrix}}{|H|}$$

The sign of the numerator in the first term is ambiguous because of the unsignable cross-partial terms: U_{12} and f_{MT}. The second term has positive sign, as proposed previously. Hence, $\frac{dT^*}{dp}$ has indeterminate sign.

However, if T and M are perfect substitutes for the production of health, we expect the first term to be positive. Then, $\frac{dT^*}{dp} > 0$. An increase in prescription price and other medical inputs would make people use greater input of time for health-improving efforts. This may be explained in another way that an increase in the effective price of

certain kinds of drugs would motivate people to search for the lower-cost medical alternatives.

6.3 Effects of the hourly income

$$\frac{dT^*}{dw} = \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & \lambda\tau & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & \lambda & U_{12} f_T & -w \\ U_{12} f_M & 0 & U_{22} & -1 \\ -(w\tau + p) & -(24 - T^0 - \tau M) & -1 & 0 \end{vmatrix}}{|H|}$$

$$= \frac{\lambda\tau(-1)|D_{12}|}{|H|} + \frac{\lambda|D_{22}|}{|H|} + \frac{-(24 - T^0 - \tau M)|D_{42}|}{|H|}$$

$$-\lambda\tau \frac{\begin{vmatrix} U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{22} & -1 \\ -(w\tau + p) & -1 & 0 \end{vmatrix}}{|H|} + \lambda \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_{12} f_M & -(w\tau + p) \\ U_{12} f_M & U_{22} & -1 \\ -(w\tau + p) & -1 & 0 \end{vmatrix}}{|H|}$$

=

$$-(24 - T^0 - \tau M) \frac{\begin{vmatrix} U_1 f_{MM} + U_{11} f_M f_M & U_{12} f_M & -(w\tau + p) \\ U_1 f_{MT} + U_{11} f_M f_T & U_{12} f_T & -w \\ U_{12} f_M & U_{22} & -1 \end{vmatrix}}{|H|}$$

The second term has a negative sign while the third term has a positive sign. The sign of the first term is ambiguous. Hence, $\frac{dT^*}{dw}$ has indeterminate sign.

APPENDIX B

Abbreviation

AFDC	Aid to Family with Dependent Children
AWP	Average wholesale price
CPI-u	Consumer Price Index-urban
CV	Covariance
EAC	Estimated acquisition cost
FDA	Food and Drug Administration
FMAP	Federal medical assistance percentage
GLS	Generalized least squares
GPI	Generic Product Identification
HCFA	Health Care Financing Administration
LSDV	Least squares dummy variable
MAC	Maximum allowable cost
MDDB	Medispan's Master Drug Database
MSIS	Medicaid Statistical Information System
NDC	National Drug Code
NPC	National Pharmaceutical Council
OBRA90	Omnibus Budget Reconciliation Act 1990
OLS	Ordinary least squares
UI	Urban Institute
WAC	wholesale acquisition cost

APPENDIX C

Glossary

Allowable drug ingredient cost

Medicaid payment basis for drug products that are not subject to MAC lists

Drug non-reimbursement rate

Percentage of drugs for a given therapeutic indication that are excluded from Medicaid reimbursement in a state but not in some other states

Generic dispensing rate

Percentage of prescriptions for a given multi-source drug that are dispensed or filled by generic drug products

Single source drug prescribing rate

Percentage of all-source prescriptions for a given drug that are prescribed and filled by the patent-protected single source drugs